EPA Reg. No. 68451-1 Vol. 2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MAY 1 4 2013

Ms Patricia Sheehy Intervet, Inc. D/.B/A Merck Animal Health 556 Morris Avenue, S5-2145A Summit, NJ 07901

Subject:

Extension of the Deadline for Submission of Efficacy Data Required as a Condition of

Registration

EPA Reg. No. 68451-1 Deltamethrin 4% Collar

Your request dated May 8, 2013

Dear Ms. Sheehy:

We considered your request for an extension of the deadline for submission of the data listed below, required as a condition of registration for the subject product under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Per your request, the deadline for submission of the subject data is extended to December 15, 2013.

Anti-feedant /Repellency for Mosquitoes (*Anopheles* sp. & *Aedes aegypti*), as specified on the Product Performance Data Evaluation Record (Sweeney, March 21, 2012) previously provided to you.

Please note that if these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e).

If you have any questions regarding this action, please contact Olga Odiott at (703) 308-9369.

Mark Sularlez

Product Manager 13 Insecticide Branch

Registration Division (7505P)

Explore Registrations	
Reg Number, 58451 1 Reg Type: Product Registr Neme: DELTAMETHRIN 4% COLLAR	ration Section 3 Status: Conditionally Registered (05-Jun-1 <view details="" registration=""></view>
Submission Type SPP Rec	o New Receipts) ∨d Date Resubhission Dassilption
☐Decisions ☐ D: Pending; 478768; 68451-1;350; GENERAL CO ☐ 75-Day Letters ☐ D: Closed; 457072; 68451-1;330; NON-FAST-7 ☐ D: Closed; 42737; 68451-1;332; NOTIFICATION ☐ D: Closed; 427000; 68451-1;332; NOTIFICATION ☐ D: Closed; 426887; 68451-1;332; NOTIFICATION ☐ D: Closed; 415181; 68451-1;332; NOTIFICATION ☐ D: Closed; 144305; 68451-1;300; LABEL REVISIO ☐ D: Closed; 144304; 68451-1;305; DATA REQUIR ☐ D: Pending; 144302; 68451-1;305; DATA REQUIR ☐ D: Pending; 144301; 68451-1;305; DATA REQUIR ☐ D: Closed; 144301; 68451-1;305; DATA REQUIR	Submission Type: Miscellaneous Receipt Resubmission? Yes No E. Sub # Decision # 478768; 350; GENERAL CORRESPONDENCE; Submitter Company: INTERVET INC Application Date: 08-May-2013 OPP Received Date: 08 May-2013 Date Sent to Risk manager: 98-May-2013 Studies Included? Yes No Fast Track? Yes No Form A Signed? Yes No None Date: Form B Signed? Yes No None Date:
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Odiott, Olga

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From: Sheehy, Patricia [patricia.sheehy@merck.com]

Sent: Wednesday, May 08, 2013 2:48 PM

To: Odiott, Olga

Subject: Extension Request for Submission of data to support Mosquito Claim

Attachments: EPA Approval Letter March 21 2012.pdf; Amblyomma -Mosquitoes REVIEW March 2012.pdf

Ms. Odiott:

I am so sorry we keep missing each other on the phone. As I mentioned in my voice mail on Tuesday May 7th, EPA found our mosquito claims acceptable for our Deltamethrin 4% Collar provided we agreed to submit additional data with the mosquito Genus Aedes (using Ae. aegypyti as the test species) and the mosquito Genus Anopheles (suggest Anopheles quadrimaculatus as the test species but other species may be justified). This was written up in the March 2012 DER.

We started working with outside contract labs last summer but due to space and scheduling with the labs and the inability to obtain the required mosquito genus during the fall and winter months—we have only just been able to initiate the required work.

At this time I would like to request EPA approval of an extension from the March 2013 due date to Dec. 15, 2013. We have a contract signed with a laboratory and a schedule of the study that confirms I will have the final report on or before the Dec. 15 2013 date requested.

Attached is a copy of the EPA letter and DER to which I am referring. We did not have the cover letter when we starting looking at labs last summer and it was just now brought to my attention that while the DER was not specific about a deadline the cover letter identified the March 2013 due date.

Pant Hopeful that EPA can approve this request. I will be in the office through Thursday May 9th 1 if you need any further information. I will be out of the office on vacation returning Monday May 20th.

With kind regards

Trish

Tess. .

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Regulatory Affairs T: (908) 473-3551 F: (908) 473-5560

e-mail: patricia.sheehy@merck.com

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MAR 2 1 2012

Ms. Heather R. Bjornson Technology Sciences Group Inc. 1150 18th Street, NW, Suite 1000 Washington, D.C. 20036

Subject:

Label Amendment to Add Efficacy Claims

EPA Reg. No. 68451-1 Deltamethrin 4% Collar

Your Submission Dated October 31, 2012

Dear Ms. Bjornson;

The labeling referred to above and submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable subject to the comments listed below.

- The mosquito claims are acceptable provided you agree to submit additional data (Guideline 810.3400), as specified on the enclosed Efficacy Review Memo (Sweeney, March 21, 2012). Such data should be submitted to the Agency by March 2013, one year from the date of this Memo.
- 2. Repellency claims for ticks are not acceptable based on the submitted data, therefore, delete the claims throughout the label.

Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). A stamped copy of the label is enclosed for your records. Two (2) copies of the final printed labeling must be submitted prior to releasing the product for shipment.

If you have questions regarding this action, please contact Olga Odiott at (703) 308-9369.

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Mark Suarez Product Manager 13

Insecticide Branch

Registration Division (7505P)

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Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

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Mark Suarez

Product Manager 13 Insecticide Branch

Registration Division (7505P)

Enclosure

page:

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revision date: 10-25-11

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Dog Collar for Flea and Tick Control SCALIBOR® Dog Collar for Flea & Tick Control.

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs SCALIBOR® 6-Month Flea and Tick Collar for Dogs SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Six Month Collar for Dogs SCALIBOR® Six Month Flea and Tick Collar for Dogs SCALIBOR® Six Month Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Long Lasting Collar for Dogs SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® Protector Band for Dogs

ACCEPTED WITH COMMENTS in EPA Letter Dated Under the Feseral Macrisone. Fungicide, and Rodenticide Act. as amended, for the pesticide registered under EPA Rey. No.

ACTIVE INGREDIENT: Percentage by Weight Deltamethrin 4.0% INERT INGREDIENTS 96.0% Total 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT. 0.9 oz.

Intervet Inc (d/b/a Merck Animal Health) Summit, NJ 07901

Product of France

Deltamethrin 4% Collar EPA Reg. No: 68451-1

page: revision date: 2 of 5 10-25-11

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

	FIRST AID					
If swallowed	If swallowed • Call poison control center or doctor immediately for treatment advice.					
	Have person sip a glass of water if able to swallow.					
	Do not induce vomiting unless told to do so by the poison control					
	center or doctor.					
	• Do not give anything by mouth to an unconscious person.					
If on skin or						
clothing	• Rinse skin immediately with plenty of water for 15 - 20 minutes.					
	• Call a poison control center or doctor for treatment advice.					
If in eyes	Hold eye open and rinse slowly and gently with water for 15	- 20				
	minutes.					
	• Remove contact lenses, if present, after the first 5 minutes, the	ien				
	continue rinsing eye.	4 4 4 4				
	• Call a poison control center or doctor for treatment advice.	6				
F	or incidents involving HUMANS, call 1-800-680-9206	5 & C				
For incidents in	ivolving ANIMALS, call 1-800-224-53181 EST between the ho	urs ôf 🏋				
	xx and xxx. Evenings and week-ends call 800-345-4735	6				
Have the produ	nct container or label with you when calling a poison control con	ter or doctor,				
	or going for treatment	(

Deltamethrin 4% Collar EPA Reg. No: 68451-1 page: 3 of 5 revision date: 10-25-11

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Wipe the collar with a damp cloth prior to application. Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time. This collar should be worn continuously. Reapply a new collar every 6 months.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

Part No. xxxxx

Universal Product Code Number (Bar Code)

Product of France



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OPTIONAL/ALTERNATE LABEL TEXT

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology.

Fleas (Ctenocephalides sp.) on the dog will be killed and those present in the dog's environment that may infest your pet will be killed.

Collar will kill and repel ticks for up to 6 months including: Lone Star tick (Amblyomma americanum), Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis), and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease.

Kills fleas and ticks for up to 6 months

Long lasting protection for up to 6 months

Protects your dog from (fleas) and (ticks) for up to 6 months

Continuous protection

Kills ticks (including deer ticks which may transmit *Lyme disease*)

Kills ticks (which may transmit Rocky Mountain Spotted Fever)

Kills ticks (which may transmit anaplasmosis, babesiosis, ehrlichiosis, tularemia, Lyme disease and Southern Tick-Associated Rash Illness (STARI)

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name kills fleas and may reduce the incidence of FAD

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit babesiosiss [10]

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit anaplasmosiss;

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

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Deltamethrin 4% Collar EPA Reg. No: 68451-1

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OPTIONAL/ALTERNATE LABEL TEXT (cont'd)

Not affected by water

Water resistant

Repels mosquitoes for up to six months.

Reduces mosquito bites for up to six months.

Reduces blood feeding by mosquitoes for up to six months.

Protects against mosquito bites for up to six months.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM:

To: Olga Odiott

From: Kevin Sweeney, Senior Entomologist

Date: March 21, 2012

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 396235 Decision no.: 457072 Submission no: 906189 Action code: R340

Product Name: Deltamethrin 4% Collar EPA Reg. No or File Symbol: 68451-1 Formulation Type: RTU dog collar

Ingredients statement from the label with PC codes included: 4% deltamethrin (w/w) (PC

code: 097805)

Use pattern: dog collar for use against fleas, ticks and mosquitoes

Application rates of product/active ingredient: RTU dog collar with claims of 6 months

longevity

OCSPP Guideline 810.3300

I. Action Requested: Review two studies and the new product label. Registrant requests the addition of the Lone star tick to the label and mosquito claims.

II. Background: The subject product is a registered dog collar. The registrant submitted two MRIDs in support of the subject amendment. One study evaluated the repellency and kill efficacy of the collar against Lone star ticks and fleas. The second study assessed the anti-feedant properties against one adult mosquito species, *Culex pipiens pipiens*.

III. Study reviews:

1. MRID 48646602 Hair, J.A. 2011. Efficacy and Repellency of Scalibor Collar for the Prevention of Tick (Amblyomma americanum) and Flea (Ctenocephalides felis) on Dogs.

This study was done in accordance with GLP except that fed and water sample testing for pesticides was not done according to GLP and the testing facility did not have the staff to oversee the work of the study director because it was a small business.

Purpose: To assess the subject product for: 1) kill efficacy of the against Lone Star ticks and fleas; and 2) the repellent activity against Lone Star ticks.

Materials and Methods:

Study location: Nu-Era Farms, 320 N. Range Road, Stillwater, OK 74075

Test substance: Scalibor collar - 4% (w/w) deltamethrin

Control substance: untreated placebo collar

Test companion animals: Beagle breed dogs from Nu-Farm dog colony. The 22 dogs used in the study consisted of 11 males and 11 females. Based on pre-study to evaluate tick infestation, 20 dogs were selected – 10 males and 10 females. All dogs had short-hair and ranged in age from 4-7 years. During infestation each animal was housed in its own cage.

Test conditions: 62-97 F

Test species: Adult life stage of the Lone Star tick, Amblyomma americanum, and cat flea (Ctenocephalides felis). Study director presumed a sex ratio of 1:1 for the ticks.

Tick study experimental design: randomized complete block design with pre-treatment counts as a blocking factor. The experimental unit (replicate) was a dog and there were two treatments (n = 10 for each): a 4% deltamethrin dog collar treatment and untreated placebo control treatment. Twenty-two dogs were screened for attractiveness to Lone Star ticks and the 20 most attractive dogs were used in the study. There were ten randomly assigned blocks of two dogs each and the treated dog in each block was also assigned at random.

Tick repellency evaluation: Dogs were exposed to 50 free ranging ticks placed in the chamber with them for two hours. Tick repellency was evaluated on days 23, 75, 13 and 187 post-treatment. Repellency was evaluated for up to 48 hours post-exposure.

Tick efficacy evaluation: 50 ticks were placed in the chamber. Dogs were exposed to ticks in the infestation chamber for 4 hours on days 14, 28, 56, 89, 118, 147 and 180. Efficacy was evaluated at the end of a 48 hour period on days 16, 30, 58, 91, 120, 149 and 182.

For ticks, at least 25% of ticks had to attach to the control animals for the control and treated

results to be considered.

Fica experimental design: randomized complete block design with pre-treatment counts as a blocking factor. The experimental unit was a dog and there were two treatments (n = 10 for each): a 4% deltamethrin dog collar treatment and untreated placebo control treatment.

Flea efficacy evaluation: Dogs were infested with 100 newly emerged unfed fleas each on days 15, 29, 57, 90, 119, 148 and 181. Efficacy was evaluated over a 24 hour period on days 16, 30, 58, 91, 120, 149 and 182.

Data points reported:

- Tick efficacy: number of live ticks found on dogs at 48 hours post tick exposure.
- Tick repellency: number of ticks recovered in the cage (live and dead) plus number of unattached tick dead ticks on the dog.
- Flea efficacy: number of live fleas recovered from each dog at 24 hours post flea exposure.

Data analysis: data were log transformed. A mixed linear model with repeated measures was used to analyze the data. The repeated measures were treatment, day, and treatment*day as fixed effects with block and block*treatment as random effects. Least square means were used for means comparisons and back transformed to obtain geometric means. A Kenward-Roger's adjustment was used to determine the denominator degree of freedom for hypothesis. Akaike's Information Criterion (AIC) was used as the criterion to select the covariance structure for repeated measures. SAS 9.1.3 was used. The level of significance was p ≤ 0.05

Major deviations: There were 4 amendments listed in the study and three deviations. In addition, dog collar attachment was reported in the results but collar replacement not listed as a deviation from the protocol. Dog collars were removed and replaced on many treated and untreated dogs due to irritation or breakage from trying to scratch them off. The study does not discuss the effect of these changes on study results or longevity of efficacy. The dates of collar change were not reported. Per the Agency's request, Intervet has agreed to amend the study to discuss this issue. The registrant explained by personal communication that in nearly every case the same collar was used as a replacement and that the collar replacement did not impact study results.

Results:

Following tick infestations, not all ticks were recovered at the end of the exposure and evaluation periods. The tick attachment rate in the study for the untreated control dogs ranged from 31-40%.

Tick efficacy:

• Untreated control dogs had infestation rates of 28-54%. This translated into a mean of 14-28 ticks per dog from the 50 ticks used to infest the chamber.

• Tick kill on dogs was 98.5% or higher through 6 months

Flea efficacy:

- Untreated control dogs had infestation rates of 62-72%. This translated into a mean of 62-72 fleas per dog.
- Flea kill on dogs was 99% through 6 months.

Tick repellency:

• Repellency was 80% or less during the course of the study.

Conclusions: The study is acceptable. The results support a six month kill claim against fleas and the Lone Star tick. The study does not support a repellency claim against ticks.

Comments on study conduct:

- Collar replacement should be better documented and the effects on study results described. This should also be reported as a deviation from the protocol.
- Live crawling ticks and attached ticks (live or dead) should be considered as not repelled. Unattached dead ticks or ticks not on the animal but recovered in the cage may be considered as repelled. EPA believes that any tick attached to a dog is not repelled.

2. MRID 48646601 Franc, M. 2004. A Pivotal Clinical Study to Assess the Anti-Feeding Effect of Scalibor Protector Band (4% w/w deltamethrin) on Adult Female Mosquitoes Culex pipiens pipiens on Dogs. (Nat. Veterinary School, Toulouse, France)

This is not a GLP study but conforms to Good Clinical Practice (GCP).

Purpose: To assess the anti-feedant effects of a 4% deltamethrin dog collar (Scalibor) against Cx. pipiens pipiens mosquitoes.

Materials and Methods

Study location: National Veterinary School, Dept. of Public Health, Deramatology-Parasitology, Toulouse, France

Test substance: Scalibor collar- 4% (w/w) deltamethrin

Untreated control: No collar appeared to be used.

Test companion animals: Beagle dogs. The 20 dogs used in the study consisted of 8 males and 12 females. Based on a pre-study to evaluate attractiveness to mosquitoes, the dogs were ranked in order of attraction. All dogs had short-hair and ranged in age from 3-4 years. During

mosquito exposure each animal was sedated and placed in a room by itself. Treated and control animals were placed in separate rooms during mosquito evaluations.

Test conditions: "environmentally controlled" with temperature, relative humidity and photoperiod not reported in the study but retained on the raw data sheets.

Test species: Adult Cx. pipiens pipiens mosquitoes that were 1-4 weeks old. Mosquitoes were not fed for at least 48 hours before exposure to dogs. The mosquito strain used was susceptible to deltamethrin and adapted to feeding on dogs since this mosquito species usually prefers birds.

Experimental design: Randomized design and dogs were paired with another dog of equal susceptibility to mosquitoes and assigned to treatments as described in the study (Sec 6.2 on page 7 of 19). Testing was done in two parts, each with 4 treated, 4 untreated and 2 reserve dogs (one treated and one untreated) in each study part. Dogs were sedated during testing, placed in a mosquito net structure in the room and exposed to 50 female mosquitoes for 1.5 hours. Dogs were removed at the end of this time. After the dogs were removed, the mosquitoes were fed sugar or honey water through 48 hours post-exposure. Mortality and blood feeding status were assessed at 18-24 hours and at 48 hours exposure.

Data were pooled from replicates in each treatment. Data points reported included: 1) live and engorged mosquitoes; 2) live and unengorged; 3) dead and engorged; and 4) dead and unencorged. The study was conducted for 27 weeks. Data points were reported from weekly exposure intervals at weeks 1, 24, 9, 13, 16, 20, 25, and 27.

Data analysis: The four data points were calculated for treated and untreated data. Treatment and category means were compared.

Results:

- Over 99% of the mosquitoes did not feed on the treated dogs.
- The deltamethrin treatments did result in mortality values of over 60% in the treatments for most of the study weeks. However, dead mosquitoes were not engorged.
- Untreated control mortality was 2% or less throughout the study.

Conclusion: The study is acceptable. The results show that the 4% deltamethrin collar reduced feeding by mosquitoes exposed to treated dogs and supports anti-feedant and repellency claims. Data was only submitted for one mosquito species and conditional data should be required for *Aedes aegypti* and an *Anopheles* sp. mosquitoes.

IV. Entomologist's Recommendations:

- 1. The studies are acceptable. The registrant will amend MRID 48646602 to fully document collar replacements and the lack of effect on study results.
- 2. The addition of the Lone Star tick and associated kill claims to the label are acceptable.
- 3. Tick repellency claims are not acceptable based on the data submitted for the Lone Star tick.
- 4. The mosquito claims listed on the label are acceptable provided the registrant agrees to conduct a study with the mosquito Genus Aedes, (using Ae. aegypti as the test species), and the mosquito Genus Anopheles, (suggest Anopheles quadrimaculatus as the test species but other species may be proposed and justified.)
- 5. The remaining label claims presented in this amendment together with past claims added by notification are acceptable.

page: 1 of 5 revision date: 10-25-11

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Dog Collar for Flea and Tick Control SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs

SCALIBOR® 6-Month Flea and Tick Collar for Dogs SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs SCALIBOR® Six Month Flea and Tick Collar for Dogs

SCALIBOR® Six Month Flea & Tick Collar for Dogs

ACTIVE INGREDIENT: Percentage by Weight
Deltamethrin 4.0%
INERT INGREDIENTS 96.0%
Total 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

Intervet Inc (d/b/a Merck Animal Health) Summit, NJ 07901

Product of France

Deltamethrin 4% Collar EPA Reg. No: 68451-1 page:

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revision date:

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on pupples under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

FIRST AID					
 Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. 					
 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice. 					
 Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, therefore continue rinsing eye. Call a poison control center or doctor for treatment advice. 					
For incidents involving HUMANS, call 1-800-680-9206 For incidents involving ANIMALS, call 1-800-224-53181 EST between the hours of xxx and xxx. Evenings and week-ends call 800-345-4735. Have the product container or label with you when calling a poison control center or doctor, or going for treatment					

Deltamethrin 4% Collar EPA Reg. No: 68451-1 page: 3 of 5 revision date: 10-25-11

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Wipe the collar with a damp cloth prior to application. Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time. This collar should be worn continuously. Reapply a new collar every 6 months.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets. **Pesticide and Container Disposal:** Do not reuse container or used collar. Dispose of in trash.

Part No. xxxxx

Universal Product Code Number (Bar Code)

Product of France

page: 4 of 5

revision date: 10-25-11

OPTIONAL/ALTERNATE LABEL TEXT

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology.

Fleas (Ctenocephalides sp.) on the dog will be killed and those present in the dog's environment that may infest your pet will be killed.

Collar will kill and repel ticks for up to 6 months including: Lone Star tick (Amblyomma americanum), Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis), and door ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease.

Kills fleas and ticks for up to 6 months

Long lasting protection for up to 6 months

Protects your dog from (fleas) and (ticks) for up to 6 months

Continuous protection

Kills ticks (including deer ticks which may transmit Lyme disease)

Kills ticks (which may transmit Rocky Mountain Spotted Fever)

Kills ticks (which may transmit anaplasmosis, babesiosis, ehrlichiosis, tularemia, Lymc disease and Southern Tick-Associated Rash Illness (STARI)

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name kills fleas and may reduce the incidence of FAD

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit babcsiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Deltamethrin 4% Collar EPA Reg. No: 68451-1 page: 5 of 5

revision date: 10-25-11

OPTIONAL/ALTERNATE LABEL TEXT (cont'd)

Not affected by water

Water resistant

Repels mosquitoes for up to six months.

Reduces mosquito bites for up to six months.

Reduces blood feeding by mosquitoes for up to six months.

Protects against mosquito bites for up to six months.



Summary of Discussion/March 19 2012/Deltamethrin Collar Efficacy Study Sheehy, Patricia

Kevin Sweeney 03/20/2012 04:45 PM

"Heather Bjornson (HBjornson@TSGUSA.COM)"

Hide Details

From: "Sheehy, Patricia" <patricia.sheehy@merck.com>

To: Kevin Sweeney/DC/USEPA/US@EPA

Cc: "Heather Bjornson (HBjornson@TSGUSA.COM)" <HBjornson@TSGUSA.COM>

Mr. Sweeney:

My apologies for getting this out to you so late today but as promised I am sending this communication to confirm our discussion yesterday with regard to our efficacy submission for our Deltamethrin Collar, EPA Reg No 68451-1 (Ref. MRID48646602): Efficacy and Repellency of Scalibor Collar for the Prevention of Tick (Amblyomma americanum) and Flea (Ctenocephalides felis) Infestations in Dogs.

Your March 19, 2012 email to Heather Bjornson indicated the following: In this study, the director reported the reapplication of dog collars to the test animals (page 24). The study was conducted for 6 months but as described in Table 5 (Page 29) only two treated dogs were the original collar throughout the study. The rest of the treated dogs had collars replaced from 2-4 times.

In table 5, the weight of the replaced collar (including residual pieces for fitting) is deducted from the weight of the original collar and expressed as applied weight? Collars used as replacements were not aged. Therefore, there is some kind of assumption, which I don't understand, that the collars will release deltamethrin at the same rate every day of the study. This seems unlikely at best because the temperature during the in-life phase of the study varied by as much as 30 degrees F. Release rate from the collars and tick flea activity is likely to be affected by ambient temperature. The temp was not the same in the study and it should have been.

Older Deltamethrin studies, previously reviewed by the Agency, have supported the 6-month efficacy duration of this collar. The reason the collars were removed and replaced on the dogs is that these dogs were not used to having collars on and as a result after initial application, tended to scratch the area so frequently some dogs the collars came off their necks. In most cases the same collar was put back on the dog but in a few cases the dogs actually broke the clasp and the collars had to be replaced.

Taking into consideration what we know about the slow release of the material from the collar, equilibrium of the deltramethrin over the dogs body is maintained even if a new collar is applied. Previous studies on release of the material show that release rate is dependent upon friction and environmental conditions.

These dogs were kept in an indoor barn with fans and was designed more to ensure field conditions. The collars were not aged. Again the release of material and spread over the dog's entire body being based on the amount of friction and amount of material released and necessary to ensure equilibrium. As the material gets washed off, additional material is released from the collar. Our assumption is not that the same amount of deltamethrin is released at the same rate every day but rather deltamethrin is released as needed on a daily basis and can differ from dog to dog.

I agree that our final study report could have provided more detail in addressing your questions. It is our intention to provide an amended report to EPA to ensure that clarification is provided and is documented to the points we discussed yesterday.

Please let me know if you need any further clarification

With kind regards

Trish

Regulatory Affairs

T: (908) 473-3551 F: (908) 473-5560

e-mail: patricia.sheehy@merck.com

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DATA PACKAGE BEAN SHEET

Date: 17-Nov-2011
Page 1 of 2

Decision #: 457072

DP #: (396235)

PRIA

Parent DP #:

Submission #: 906189

E-Sub #:

* * * Registration Information * * *

Registration:	68451-1 - DELTA	METHRIN 4% COLLAI	₹		-
Сотрапу:	68451 - INTERVET IN	ıc			_
Risk Manager:	RM 13 - Mark Suarez	- (703) 305-0120 Room# PY	1 S-7246		
Risk Manager Reviewer:	Olga Odiott OODIOTT	-			
Sent Date:		Calculated Due Da	ate: 22-Mar-2012	Edited	Due Date:
Type of Registration:	Product Registration -	Section 3			
Action Desc:	(R340) NON-FAST-TE	RACK (INCLUDES CHANGE	S TO PRECAUTION	ARY LABEL STATEME	
Ingredients:	097805, Deltamethrine	(4%)			-
	* ;	* * Data Package Ir	nformation * *		PLACE CONTRACTOR CONTR
Expedite:	◯ Yes ● No	Date Se	ent: 17-Nov-2011	1	Due Back:
DP Ingredient:	097805, Deltamethrin				-
DP Title:					_
CSF Included:	() Yes No	Label Included:	○ No Parent	: DP #:	
Assigned To	<u>0</u>	Date In	Date Out		
Organization: RD / II	3		—	Last Possible Science	Due Date: 21-Feb-2012
Team Name: Efficac	cy (IB)			Science	Due Date:
Reviewer Name:				Sub Data Package	Du e Date:
Contractor Name:					

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Attached for your review dat submitted to support adding label claims of efficacy for up to 6 months.

Page 2

**	Page 2	3
DP#: (396235)	* * * Studies Sent for Review *	** Decision#: (457072)
MRID MRID	Sictus Citation Reference	Guidéline (10-5 Status
48646601	Franc, M. (2004) A Pivotal Clinical Study to Assess the Anti-feeding Effect of Scalibor Protector Band (4% W/W Deltamethrin), on Adult Female Mosquitoes Culex pipiens, on Dogs. Project Number: V/0193/0772. Unpublished sludy prepared by National Veterinary Institute. 79p.	810.3300/Treaments to control pests of humans and pets
48646602	Hair, J. (2011) Efficacy and Repellency of Scalibor Collar for the Prevention of Tick (Ambiyomma americanum) and Flea (Ctenocephalides felis) Infestations on Dogs. Project Number: N10/032/01. Unpublished study prepared by Nu-Era Research Farms. 72p.	810.3300/Treatments to control pests of humans and pets

Decision Seq. 457072	Action Code: K340,ROB-FAST-1	TRACK (INCLUDES CHANGES TO PR	GECAUIT	Decision Status
ntative Start Date 22-Nov 2	2011 Terrtative Ind. Yes	FFS Original Decision.		Tracking
entative Dus Date 22-Mar 2	2012 75-Day Due Dete	FFS EUP Decision		Create Resubmission
PP Target Due Dt.	21-Day Screen Dt: 22-1	Nov-2011 FFS Primary Decision:	223	FFS Letters
legotiated Due Dt		Start/Stop Clock FQPA Clock:		เหมาะ บระกัดตาลวัดห
Registrant	[ij]	Days Elepsed:		Action Code History
Current Status: PENDING	(D1 Noy-2011)			Secondary Decision
∄ Decision Comments Meetings & Milestones	Payment > UFFS Information	Unmaiched Payments © FFS Negotiated Due Dates	75 Day Left	A Company of the Comp
Decision Ownership	Receipts	Deta Package	Reduced R	Aliande, la villa de la compania de
Receipis	Statt Member	Reg/DC/Number Submission Du	eta[277]	Response
3 S:906189 Odiott Olg	a 11 12 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	3451-1 j 22-Mar-201	2 PENDING	
Addition Came of em	cacy for up to 6 months			

Memorandum

Date:	11 / 03 / 11	
To:	Pri 13	, Regulatory Manager
From:	Information Services	Branch, ITRMD
indicati	our receipt of this data sion that MRIDs for the osted to OPPIN.	
from tl	•	e approximately 5 days the study-level data is
-	you have any questions contact Teresa Downs	~
This is	/ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	pted submission

PRIA 2 – 21 Day Content Screen Review Worksheet (EPA/OPP Use Only)

21 Day Screen Start Date:	10 - 3	1-11			/
Experts In-Processing Signature:		HARRINGTON	Date //-/- //	Fee Paid:	Yes 🔟
Division management contacted	on issues N	loYes	Date		
					

EPA	Reg. Number: 68451-1	EPA Receipt Date:	10 -	3/-	11		
	Items for I	Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1 including package type	()(link to form) signed & co	mplete		X		
•	Confidential Statement of Formula a dated (EPA Form 8570-4) (Link to for	2	igned, a	nd			X
2	a) All inerts (link to http://www.epa.g including fragrances, approved t Footnote A)	- · · ·	yes	no			
3	Certification with Respect to Citation form) completed and signed (N/A if 10)-34) (L:	ink to	X		
	Certificate and data matrix consistent				· X		
	If applicant is relying on data that are of to pay statement included. (see Footno	•	yes	no			
4	If applicable, is there a letter of Author Formulator's Exemption Statement completed and signed (N/A if source is technical)	(EPA Form 8570-27) (Link	to form	•			X
	Data Matrix (EPA Form 8570-35) (Li copies (PR 98-5) (Link to PR 98-5) correpack)	-		nal	· ×		
5	a) Selective Method (Fee category ex	perts use)	yes	no			
	b) Cite-All (Fee category experts use)						
	c) Applicant owns all data (Fee categ	gory experts use)			100		
6	5 Copies of Label (link to http://www.epa.gov/pesticides/regulating/r)	aged and guidance is avail	able)(l	ink to	X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)		10 mg	X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C. a) List study (or studies) not included with application			
10				

KC. 1-2-11

Comments:

186.5: Associated studies have passed 86.5 review.

D Inerts: No inerts to review.

Documentation: Page

Pass

MRID 486466

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are strongly encouraged to verify that all inert ingredients have been approved for the application's uses even if a product is currently registered by consulting the inert Web

^{*} N/A – Not Applicable

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
 number, providing documentation that the inert has been approved, or
 removing the unapproved inert from the CSF or replacing it with one that is
 approved for the application's uses; or
- Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
 number, providing documentation that the inert has been approved, or
 removing the unapproved inert from the CSF or replacing it with one that is
 approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
- 3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

- B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.
- C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

November 07, 2011

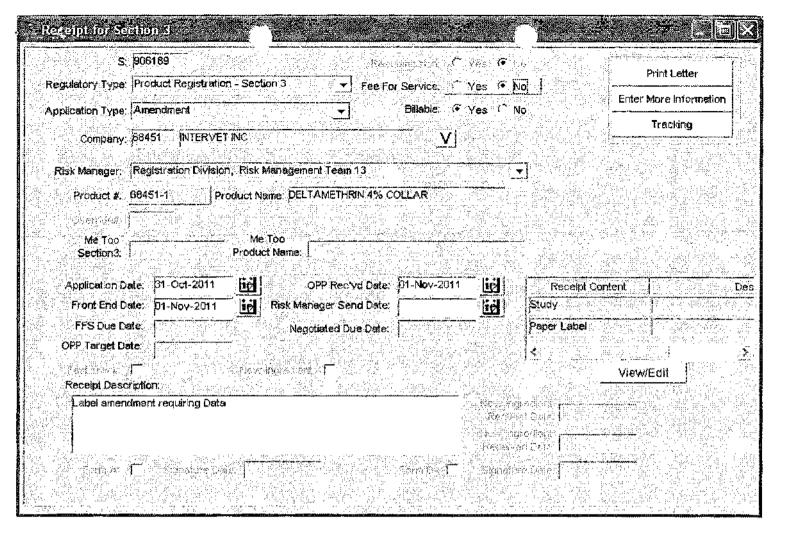
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

INTERVET INC 556 MORRIS AVENUE, S5-2145A SUMMIT, NJ 07901

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 01-NOV-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.





Technology Sciences Group Inc.

1150 18th Street, NW, Suite 1000 Washington, D.C. 20036 Direct: (202) 828-8945 Fax: (202) 872-0745 E-Mail: hbjprnson@tsgusa.com

Heather R. Bjornson Senior Regulatory Consultant

October 31, 2011

Mark Suarez
Registration Division, PM 13
Office of Pesticide Products, US EPA
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: Deltamethrin 4% Collar (EPA Reg. No. 68451-1)

PRIA Category R340 - Amendment Requiring Data

Dear Mr. Suarez:

Technology Sciences Group Inc., on behalf of Intervet, Inc., is submitting the enclosed amendment to add additional claims for the product being efficacious for up to 6 months. Along with this amendment, data is being submitted to substantiate these new claims. You will find the following included to support this amendment:

- 1. Amendment application form,
- 2. Certification with respect to data citation,
- Data matrix (confidential and non-confidential versions),
- 4. One copy of the proposed label (highlighted),
- Three copies of the revised clean label,
- 6. Data Volumes 1 through 3 (refer to the transmittal document for additional information), and
- PRIA pre-payment receipt Pay.gov tracking ID: 254Q0ASI; Agency Tracking ID: 74249677715.

275 Stater St., Suite 900 Ottawa, Ontario K1P 5H9 Phone: (613) 247-6285₃₇

โลกาตล

Davis, CA 95616 Phone: [530] 757-1245 Should you have any questions or comments, please do not hesitate to contact me directly.

Sincerely,

Heather R. Bjornson

batha R By

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VOLUME 1 of 3

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

Intervet Inc D/B/A Merck Animal Health 556 Morris Avenue, S5-2145A Summit, New Jersey 07901

2. REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Application for a Label Amendment with Data

PRIA Category: R340

Product Name: Deltamethrin 4% Collar, EPA Reg. No: 68451-1

3. TRANSMITTAL DATE

October 31, 2011

4. LIST OF SUBMITTED DOCUMENTS (3 copies of each volume)

VOLUME 1

Transmittal Document

48646601 VOLUME 2

A Pivotal Clinical Study to Assess the Anti-Feeding Effect of Scalibor Protector Band (4% Deltamethrin), On Adult Feeding Mosquiteos Culex Pipiens, On Dogs. Study No. V-0193-0772

Guideline 810.3300

48646602 VOLUME 3

Efficacy and Repellency of Scalibor® Collar for the Prevention of Tick (Amblyomma americanum) and Flea (Ctenocephalides felis) infestations

on Dogs Study Number: N10-032-01

Guideline 810.3300.

5. COMPANY NAME:

Intervet Inc. D/B/A Merck Animal Health

556 Morris Avenue, S5-2145A Summit, New Jersey 07901

6. COMPANY OFFICIAL:

Heather R. Bjornson

Senior Regulatory Consultant

7. SIGNATURE

Page 1 of 1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

November 1, 2011

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

OPP Decision Number: D-457072

EPA File Symbol or Registration Number: 68451-1 Product Name: DELTAMETHRIN 4% COLLAR

EPA Receipt Date: 01-Nov-2011 EPA Company Number: 68451 Company Name: INTERVET INC

PATRICIA A. SHEEHY INTERVET INC D/B/A MERCK ANIMAL HEALTH 556 MORRIS AVENUE, S5-2145A SUMMIT, NJ 07901-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL STATEMENTS; SOURCE CHANGES TO AN UNREGISTERED SOURCE);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

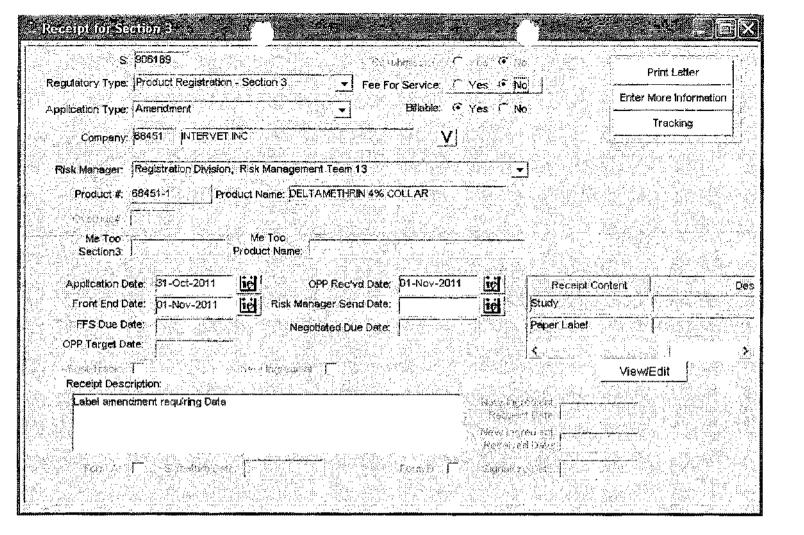
Sincerely,

Front End Processing Staff

Information Technology & Resources Management Division



This package includes the following	for Division
New Registration	○ AD
Amendment	○ BPPD ○ RD
Studies? □ Fee Waiver?	
volpay % Reduction:	Risk Mgr. 13
Receipt No. S-	906189
EPA File Symbol/Reg. No.	68451-1
Pin-Punch Date:	10/31/2011
This item is NOT subject t	o FFS action.
Action Code:	Parent/Child Decisions:
Requested: 72340	
Granted: R340	
Amount Due: \$	
☐ Inert Cleared for Intended Use	Uncleared Inert in Product
Reviewer:	> Date: 1\ - \ - \ \
Remarks:	



Heather Bjornson

From:

paygovadmin@mail.doc.twai.gov

Sent:

Thursday, October 27, 2011 11:28 AM

To: Heather Bjornson

Subject:

Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Transaction Summary

Application Name: PRIA Service Fees Pay.gov Tracking ID: 254Q0ASI Agency Tracking ID: 74249677715

Transaction Type: Sale

Transaction Date: Oct 27, 2011 11:27:45 AM

Account Holder Name: Heather R. Bjornson Transaction Amount: \$3,617.00 Billing Address: 1150 18th Street, NW Billing

Address 2: Ste. 1000 City: Washington State/Province: DC Zip/Postal Code: 20036

Country: USA

Card Type: AmericanExpress

Card Number: **********1436

Decision Number:

Registration Number: 68451-1

Company Name: Intervet Inc. D/B/A Merck

Company Number: 68451

Action Code: R340





Technology Sciences Group Inc. 1150 18th Street, NW, Suite 1000 Washington, D.C. 20036 Direct: (202) 828-8945

Fax: (202) 872-0745

E-Mail: hbjornson@tsgusa.com

Heather R. Bjornson Senior Regulatory Consultant

October 31, 2011

Mark Suarez
Registration Division, PM 13
Office of Pesticide Products, US EPA
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: Deitamethrin 4% Collar (EPA Reg. No. 68451-1)

PRIA Category R340 - Amendment Requiring Data

Dear Mr. Suarez:

Technology Sciences Group Inc., on behalf of Intervet, Inc., is submitting the enclosed amendment to add additional claims for the product being efficacious for up to 6 months. Along with this amendment, data is being submitted to substantiate these new claims. You will find the following included to support this amendment:

- 1. Amendment application form,
- Certification with respect to data citation,
- Data matrix (confidential and non-confidential versions),
- One copy of the proposed label (highlighted),
- Three copies of the revised clean label,
- Data Volumes 1 through 3 (refer to the transmittal document for additional sinformation), and
- PRIA pre-payment receipt Pay.gov tracking ID: 254Q0ASI; Agency Tracking ID: 74249677715.

. pecks

Should you have any questions or comments, please do not hesitate to contact me directly.

Sincerely,

Heather R. Bjornson

batha R By

45

VOLUME 1 of 3

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

Intervet Inc D/B/A Merck Animal Health 556 Morris Avenue, S5-2145A Summit, New Jersey 07901

2. REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Application for a Label Amendment with Data

PRIA Category: R340

Product Name: Deltamethrin 4% Collar, EPA Reg. No: 68451-1

3. TRANSMITTAL DATE

October 31, 2011

4. LIST OF SUBMITTED DOCUMENTS (3 copies of each volume)

VOLUME 1

Transmittal Document

48646601 VOLUME 2

A Pivotal Clinical Study to Assess the Anti-Feeding Effect of Scalibor Protector Band (4% Deltamethrin), On Adult Feeding Mosquiteos *Culex Pipiens*, On Dogs. Study No. V-0193-0772

Guideline 810.3300

48646602 VOLUME 3

Efficacy and Repellency of Scalibor® Collar for the Prevention of Tick (Amblyomma americanum) and Flea (Ctenocephalides felis) infestations

on Dogs Study Number: N10-032-01

Guideline 810.3300.

5. COMPANY NAME:

Intervet Inc. D/B/A Merck Animal Health

556 Morris Avenue, S5-2145A Summit, New Jersey 07901

6. COMPANY OFFICIAL:

Heather R. Bjornson

Senior Regulatory Consultant

7. SIGNATURE

Page 1 of 1

100

Please road instructions	on reverse before compli	sting form.	F	orm Approve	d, OMB No. 20	70-0060	. Approval expires 2-28-9
SEPA Environmental Protection Agend Washington, DC 20460			incy	~	Registrati Amendm Other		OPP Identifier Number
		Application for	Pesticide	- Section	1 1		
1. Company/Product Nur 68451-1	mber		2. EPA Prod Mark Sua	uct Meneger 'CZ	***************************************] p,	posed Classification None Restricted
4, Compeny/Product (Na Deltamethrin 4% Co			PM# 13				HOIV HOSOIGLEG
Intervet, Inc. D/B// 556 Morris Avenue Summit, NJ 07901		alth	(b)(i), my p to: EPA Reg.	No.		al in cor	
		Sec	HOH - H				
Amendment - Exp	response to Agency lette	r dated	Ag	el printed lab ancy letter da e Too* Appli ner - Explain i	cation.	· · · · · · · · · · · · · · · · · · ·	
	bel amendment requiring o	l; Agency Tracking ID: 74	249677715.	on via e-mail:	hbjornson@tsgu	ea.com.	
	<u></u>	Sec	tion - III				
1. Material This Product Child-Resistant Packagin Yes No Certification must be submitted	g Unit Packaging Yas No	No. per (f 'Ye		nging No. per container	1	entainer Metal Plastic Glass Paper Other (S)	pecify)
3. Location of Net Conte	nts Information Container	4. Size(s) Retail Conte		5 , L	ocstion of Label	Direction	13
6. Menner in Which Lebe		Lithograph Paper glued Stenciled		Other			
	······································		tion - IV				
1. Contact Point (Comp.	lete items directly below	for identification of indiv	idual to be co	tacted, if ne	cessery, to proc	ess this	erjoniculión.)
Name Heather R. Bjomson, ⁻	Fechnology Sciences G	Title Senior I	Regulatory Co	nsultant			Not (Include Area Code) 8945 ^{6 6 6}
	iatements I have made or t any knowlingliy false or ble law,					ir. s	6. Cate Application Received (Stamped)
2. Signature	2Bu	3. Title Regulat	ery Consultant	to intervet, in	(E :	21. 	7
4. Typed Name		5. Date	·				() () () () () () () () () ()
Heather R. Bjornson			Octobe	er 31, 201	11	}	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1200 Pennsylvania Avenue, N.W. WASHINGTON, D.C. 20460

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comments regarding burden estimate or any other aspect of this collection of information, inclu Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Aven- to this address.								
Certification with Respect to C	itation of Data							
Applicant's/Registrant's Name, Address, and Telephone Number Intervet, Inc D/B/A Merck Animal Health, 556 Morris Ave, Summit NJ 07901 / (908)	473-3551	EPA Registration Number/File Symbol 68451-1						
Active Ingredient(s) and/or representative test compound(s) Deltamethrin Date October 31, 2011								
General Use Pattern(s) (list, all those claimed for this product using 40 CFR Part 158) INDOOR		Product Name Deltamethrin 4% Collar						
NOTE: If your product is a 100% repackaging of another purchased EPA-registered submit this form. You must submit the Formulator's Exemption Statement (EPA Formulator's Exemption Statement)		r all the same uses on your label, you do not need to						
1 am responding to a Data-Call-In Notice, and have included with this form a I be used for this purpose).	ist of companies ser	nt offers of compensation (the Data Matrix form should						
SECTION I: METHOD OF DATA SUPP	ORT (Check one mo	athod only)						
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must used).								
SECTION II: GENERAL C	FFER TO PAY							
[Required if using the cite-all method or when using the cite-all option under the select I hereby offer and agree to pay compensation, to other persons, with regard to		,						
SECTION III: CERTI	FICATION							
I certify that this application for registration, this form for reregistration, or this application for registration, the form for reregistration, or the Data-Call-In response. In indicated in Section I, this application is supported by all data in the Agency's files that substantially similar product, or one or more of the ingredients in this product; and (2) in requirements in effect on the date of approval of this application if the application souguess.	addition, if the cite-a (1) concern the pro s a type of data that	all option or cite-all option under the selective method is perties or effects of this product or an identical or would be required to be submitted under the data						
I certify that for each exclusive use study cited in support of this registration the written permission of the original data submitter to cite that study.	or reregistration, tha	t I am the original data submitter or that I have obtained						
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either; (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.								
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.								
I certify that the statements I have made on this form and all attachms knowingly false or misleading statement may be punishable by fine or imprisor								
Signature RBV—	Date 10/31/2011	Typed or Printed Name and Title (Charles) Heather R. Bjørnson, Sr. Regulajory Çunsultant						

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

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		DATA MATRIX				
Date: October 31, 2011			EPA Reg. No./File Symbol: 68451-	Page 1 of 3		
Applicant's/Registrant's Name & Address: Intervet Inc., 566 Morris Avenue, Summit,		ımmit, New Jersey 07901	Product Deltamethrin 4% Collar			
Ingredient: Deltamethrin						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
830.1550	Product identification and composition	42893501	Bayer Environmental Science	PER		
830-1600	Beginning materials	42893501	Bayer Environmental Science	PER		
830-1650	Description of formulation process	42893501	Bayer Environmental Science	PER		
830-1670	Formation of impurities	42893501	Bayer Environmental Science	PER		
830-1750	Certified limits	42893502	Bayer Environmental Science			
830-1800	Enforcement analytical method	42893502	Bayer Environmental Science			
830-6302	Color	42893503	Bayer Environmental Science	PER		
830-6303	Physical state	42893503	Bayer Environmental Science	PER		
830-6304	Odor	42893503	Bayer Environmental Science	PER		
830-6314	Oxidation/Reduction		End use product does not contain a	n oxidizing ar re	ducing agent.	
830-6315	Flammability	42893503	Bayer Environmental Science	PER		
830-6316	Explodability		End use product is not potentially explosive.			
830-6317	Storage stability	42893503	Bayer Environmental Science	PER		
830-6319	Miscibility one one one		End use product is not to be diluted	with petroleum	solvents.	
Signature Roy Signature			Name and Title Patricia A. Sheehy Manager, Regulatory Affairs		Date October 31, 2011	

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		DATA MATRIX			, , ,
Date: October 31, 2011		EPA Reg. Na./File Symbol: 684	Page 2 of 3		
Applicant's/Registrant's Name (& Address: Intervet Inc., 566 Morris Avenue, S	Summit, New Jersey 07901	Product: Deltamethrin 4% Colla	ır	
Ingredient: Deltamethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-6320	Corrosion characteristics	42893503	Bayer Environmental Science	PER	în progress
830-6321	Dielectric breakdown voltage		End use product is not to be use	ed around electri	cal equipment
830-7000	pH		End use product is not to be dis	persed with wate	нг.
830-7100	Viscosity	42893503	Bayer Environmental Science		
830-7300	Density	42893503	Bayer Environmental Science PER		
870-1100	Acute oral toxicity	42389001	Bayer Environmental Science	PER	
870-1200	Acute dermal toxicity	42889002	Bayer Environmental Science	PER	
870-1300	Acute inhalation toxicity				Waiver Request
870-2400	Primary eye irritation-rabbits	42889003	Bayer Environmental Science	PER	
870-2500	Primary dermal irritation-rabbits	42889004	Bayer Environmental Science	PER	
870-2600	Skin sensitization	42889005	Bayer Environmental Science	PER	
810.3300	Product performance, efficacy	44190101	Intervet Inc.	Own	Submitted 12/26/1996
810.3300	Product performance, efficacy	44578701,44578702, 244578703, 44578704 244578705	Intervet Inc.	Own	Submitted 6/10/1998
Signature	N 0 60 50 600 80		Name and Title		Date
Signature	-K By		Patricia A. Sheehy, Manager, Reg	ulatory Affairs	October 31, 2011
					1

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		DATA MATRIX			
Date: October 31, 2011			EPA Reg. No./File Symbol: 6845	1-1	Page 3 of 3
Applicant's/Registrant's Name	& Address: Intervet Inc., 566 Morris Avenue, S	Summit, New Jersey 07901	Product: Deltamethrin 4% Collar	r	
Ingredient: Deltamethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Product performance, efficacy	44602901	Intervet Inc.	Own	Submitted 6/10/1998
870.7200	Domestic Animal Safety (dogs)	42889006	Bayer Environmental Science	PER	
810.3300	Product performance, efficacy	This submission	Intervet Inc.	Own	
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	9 A D 3 A53				
Signature Alexander	RB Francis	000	Name and Title Patricia A. Sheehy, Manager, Regu	ulatory Affairs	Date October 31, 2011

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		DATA MATRIX				
Date: October 31, 2011			EPA Reg. No./File Symbol: 68451-1	1	Page 1 of 3	
Applicant's/Registrant's Name (& Address: Intervet Inc., 566 Morris Avenue, Su	ummit, New Jersey 07901	Product Deltamethrin 4% Collar			
Ingredient: Deltamethrin						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
			Bayer Environmental Science	PER		
			Bayer Environmental Science	PER		
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			Bayer Environmental Science	PER		
			End use product does not contain a	n oxidizing or red	ucing agent.	
	6 6 6 5603		Bayer Environmental Science PER			
	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		End use product is not potentially explosive.			
	00 000 mode		Bayer Environmental Science	PER		
	500 ABB 877 A B	rcu	End use product is not to be diluted	with petroleum so	olvents.	
Signature	1 R B 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	र ट ઇ c े	Name and Title Date Patricia A. Sheehy		Date October 31, 2011	

Form Approved OMB No. 2070-0060

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Date: October 31, 2011			EPA Reg. No./File Symbol: 6845	Page 2 of 3	
Applicant's/Registrant's Name 8	k Address: Intervet Inc., 566 Morris Avenue, Sc	ummit, New Jersey 07901	Product: Deltamethrin 4% Colla	ΙΓ	
Ingredient: Deltamethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Bayer Environmental Science	PER	în progress	
			End use product is not to be use	ed around electric	al equipment.
			End use product is not to be disp	persed with water	
	Bayer Environmental Science	PER			
Per constru		· · · · · · · · · · · · · · · · · · ·	Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
**************************************					Waiver Request
			Bayer Environmental Science	PER	
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	C 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		Intervet Inc.	Own	Submitted 12/26/1996
		0 0 A 9 9 0 0	Intervet Inc.	Own	Submitted 6/10/1998
 Signaturę	0 8 808 5	?	Name and Title	ı	Date
Signature Statha R	Sp		Patricia A. Sheehy, Manager, Reg	ulatory Affairs	October 31, 2011

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		DATA MATRIX			
Date: October 31, 2011			EPA Reg. No./File Symbol: 6845	1-1	Page 3 of 3
Applicant's/Registrant's Name (& Address: Intervet Inc., 566 Morris Avenue, \$	Summit, New Jersey 07901	Product: Deltamethrin 4% Collar		
Ingredient: Deltamethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Intervet Inc.	Own	Submitted 6/10/199
			Bayer Environmental Science	PER	
			Intervet Inc.	Own	
				-	
·	5 8 5 WYD				
	7 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6				
Signature Actio	R B 100 0000	200	Name and Title Patricia A. Sheehy, Manager, Regu	latory Affairs	Date October 31, 201

MATERIAL TO BE ADDED TO JACKET

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JUL 17 2009

Ms Heather R. Bjornson Intervet Inc. 29160 Intervet Lane Milsboro, DE 19966

Subject: Label Notification(s) for Pesticide Registration Notice 2007-4 and 98-10

Storage & Disposal and other changes (Warranty Statement)

Dear Registrant:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 and 98-10 dated June 9, 2009 for:

EPA Registration 68451-1 Deltamethrin 4% Collar

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and 98-10, and finds that the label change(s) requested falls within the scope of PRN-2007-4 and 98-10. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Banza Djapao of my staff at 703-305-7269.

Sincerely,

Linda Arrington

Notifications & Minor Formulations Team Leader Registration Division (7505P)

Office of Pesticide Programs

Application for Pesticide - Section	SEPA	Environmenta	Inited States		псу	Form Approv	Registr Amend Other	ation	OPP Identifier Number
### A Company/Product (Name) ### Collision ### Delitaminhthin 4% Collision ### Supplies the Intervet Lone ### Delitaminhthin 4% Collision ### Supplies the Intervet Lone ### Milisboro, DE 19966 ### Check if this is a new address ### Check if this is a new address ### Section - III ### Amendment - Explain below. ### Amendment - Explain below. ### Amendment - Explain below. ### Product Name ### JUL 17 2009 **Section - III ### Amendment - Explain below. ### Explaination: ### Use - Explain below. ### Explaination: ### Use - Explain below. ### Explaination: ### Over - Explain below. ### Explaination below. ### Explain			Application	on for P	esticide	- Sectio	n l		<u> </u>
4. Company/Product Names Deltamethrin 4% Coliar 5. Name and Address of Applicant <i>Include 2IP Code!</i> Intervet Inc. 29160 Intervet Lane Milsboro, DE 19966 Check if this is a new address Product Name JUL 17 2009 Product Name JUL 17 2009 Section - II		ber				_	F	3. Pro	, <u> </u>
Intervet Inc. 29160 Intervet Lane Milsboro, DE 19966 □ Check if this is a new address □ Product Name □ JUL 17 2009 Section - II □ Amendment - Explain below. □ Resubmission in response to Agency letter dated □ "Me Too" Application. □ Notification - Explain below. □ Other - Other - Interventions of EPA's regulations at 40 CPR 8g 155 to 1, 156 140									nesdiciso
Amendment - Explain below. Resubmission in response to Agency letter deted	Intervet Inc. 29160 Intervet Land Milsboro, DE 19966	3	odel		(b)(i), my to: EPA Res	product is s	imilar or iden	itical in co	mposition and labeling
Resubmission in response to Agency letter deted				Sect	ion - II				
1. Meterial This Product Will Be Packaged In: Child-Resistant Packaging Yes No No No Resistant Packaging Yes No Resistant Packaging Yes No Resistant Packaging Yes No Resistant Plestic Glass Paper Other (Specify) Other (Specify) Other Section of Net Contents Information Label Container Container Lithograph Paper glited Section - IV 1. Contect Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name Heather R. Bjornson, hbjornson@tsgusa.com Regulatory Assistant Certification I certify thet the statements I have made on this form end ell attachments thereto are true, accurate end complete. I acknowledge that any knowlinglity false or misteeding statement mey be punishable by fine or imprisonment or container Certification Residual Signification Signification Significa	Resubmission in re Notification - Expla Explanation: Use additi Notification of label change the requirements of EPA's Confidential Statement of statement to EPA. I further	sponse to Agency letter in below. ional page(s) if necessar ed per PR Notice 2007-4 a regulations at 40 CFR §§ Formula for this product, runderstand that if the arr	ry. (For section and to make mind to make mind to 156.10, 156.14) understand the moded label is	inor text cha IO, 156.144, at it is a viol not consiste	tion It.) nges. This is 156.146, ar action of 18 and with the is	gency latter of Me Too" Appleton ther - Explain motification is of 156,196. No. J.S.C. Sec. 18 requirements of	dated licetion. below. consistent with cother change 9001 to willfully of 40 CFR §§ 1	the guidance s have been make any fe 56.10, 156.1	made to the labeling or the alse and misleading 40, 156,144, 156,146, and
Child-Resistant Packaging Vas Yes No **Certification must be submitted 3. Location of Net Contents Information Lebel Container Container 4. Size(s) Retail Conteiner Section - IV 1. Contect Point (Complete items directly below for identification of Individual to be contacted, if necessary, to process this application.) Name Heather R. Bjornson, hbjornson@tsgusa.com Certification Lection of Net Statements heve made on this form end all attachments thereto are true, accurate and complete. Lacknowledge that any knowlinglity false or misleading statement may be punishable by fine or imprisonment or container Since Peper Packaging A. Size(s) Retail Conteiner S. Location of Label Directions Flack of Peper Packaging Container S. Location of Label Directions Section - IV 1. Contect Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name Heather R. Bjornson, hbjornson@tsgusa.com Certification Lectification Lectification Lectification S. Drea Application Regulatory Assistant to Intervet inc. Signature 3. Title Regulatory Assistant to Intervet inc.				Secti	on - III				
Yes Yes No No No No No No No Plestic	1. Meterial This Product V	Vill Be Packaged In:		····					
Lebel Container 6. Manner in Which Lebel is Affixed to Product Paper glued Stenciled Section - IV 1. Contect Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name Title Telephone No. (trickide Area Cod Regulatory Assistant (202) 628-8945 Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. 2. Signature 3. Title Regulatory Assistant to Intervet Inc.	Yes No * Certification must	Yes No		If "Yes"	Yes Vo	No. per	2. Туре о	Metal Plestic Glass Paper	pecify}
Section - IV 1. Contect Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name Heather R. Bjornson, hbjornson@tsgusa.com Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or contacted. Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or contacted. Standard Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Title Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945 Section - IV Telephone No. (tiridude Area Cod (202) 628-8945		ts information	4. Size(s) Re	tail Contein	er l	5.	Location of Lo	bel Directio	na
Section - IV 1. Contect Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name Heather R. Bjornson, hbjornson@tsgusa.com Certification Leartify that the statements have made on this form and all attachments thereto are true, accurate and complete. Lacknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or complete. Description Stamped			Lithog Paper Stene	reph glued iled		Other			
Name Heather R. Bjornson, hbjornson@tsgusa.com Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or complete. Stamped) 2. Signature Regulatory Assistant to Intervet Inc.					on - IV				
Heather R. Bjornson, hbjornson@tsgusa.com Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or complete. 2. Signature 3. Title Regulatory Assistant to Intervet Inc.	1. Contect Paint (Comple	te items directly below t	for identification	n of individ	lual to be c	ontacted, if n	ecessery, to p	rocess this	application.)
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2. Signature Regulatory Assistant to Intervet Inc.	Lacknowledge that	any knowlinglly false or	this form end	ell attechn				ntor co	Received (Stamped)
4. Typed Name	soledna R	Br		Regulator	y Assistant (o Intervet Inc.	-/	3 K	7 6 6 6 C

Heather R. Bjornson

June 9, 2009

Please rand instructions on reverse before complete form.		PORTI ADD	reved. Umg No.	2070-006	O. Approval expires 2-28-9		
United Ste	des		Registra	ation	OPP Identifier Number		
SEPA Environmental Prote	ction Ager	ncy	Amendi				
Washington, DC	_	1	✓ Other	******			
Applio	ation for D	esticide - Sect					
	1			1. 3.			
1. Company/Product Number 68451-1		2. EPA Product Mana Kimberly Nesci	iger	3. Pr	oposed Classification		
	·····				None Restricted		
4. Company/Product (Name) Deltamethrin 4% Collar		PM# 13			-		
5. Name and Address of Applicant (Include ZIP Code)	1	•			FIFRA Section 3(c)(3)		
Intervet Inc.			s similar or ident	ical in co	mposition and labeling		
29160 Intervet Lane	***************************************	to: EPA Reg. No.					
Milsboro, DE 19966	1	EFA Negi Hui					
Check if this is a new address		Product Name _					
	Sect	tion - II					
Amendment - Explain below,		Final printed	lebels in repsons	e to			
		Agency latte	er dated				
Resubmission in response to Agency fetter dated		*Me Too* A	pplication.				
Notification - Explain below.		Other - Expla	ain below.				
Explanation: Use additional page(s) if necessary. IFor se	ection I and Sac	tion II i					
Notification of label changed per PR Notice 2007-4 and to make			- cannintant with t	aachim ee	- > DD Steller 2007. A and		
PR Notice 98-10 and the requirements of EPA's regulations at	140 CFR §§156.1	10, 156.140, 156.144, 1	!56.146, and 156.1	56. No othe	er changes have been made		
to the labeling or the Confidential Statement of Formula for this and misleading statement to EPA. I further understand that if the							
156.144, 156.146, and 156.156, this product may be in violatic							
of FIFRA.	·						
	Secti	ion - III					
1. Meterial This Product Will Be Packaged In:							
Child-Resistant Packaging Unit Packaging	Water S	r Soluble Packaging 2. Type of Conteiner					
Yes Yos	· [[] `	Yes			Metal Plastic		
✓ No ✓ No	<u> </u>	No			Glass		
* Certification must If "Yes" No. pe		s" No. per			Papar		
ba submitted Unit Packeging wgt. contain	ner Package				Specify)		
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Lebel Container	1 collar, 0						
6. Manner in Which Lebel is Affixed to Product P. S.	ithograph apar glued itanciled	Other	***************************************				
		on - IV		······	<u> </u>		
1. Contact Point (Complete items directly below for identifi		<u> </u>	f necessery, to pr	ooess this	anplication.)		
	Title				e No. (Include Aree Code)		
Name Heather R. Bjornson, hbjornson@tsgusa.com		ry Assistant		(202) 828			
Cert	ification				5. Data Application		
I certify that the statements I have made on this form	and all attachm				Received		
I scknowledge that any knowlingly faize or misleading statement may be punishable by line or imprisonment or (Stamped)							
both under applicable law.							
2. Signeture	3. Title						
deturk B	Regulatory	y Assistant to Intervet Ir	1C.				
4. Typed Name	5. Date						
Heather R. Bjornson July 7, 2009							



WASHINGTON

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036 Telephone 202 223-4392

Fax 202 872-0745

Kimberly Nesci

Registration Division (7504P) Office of Pesticide Products

U.S. Environmental Protection Agency Room S-4900, One Potomac Yard

2777 South Crystal Drive Arlington, VA 22202-4501 June 9, 2009

RE: Deltamethrin 4% Collar (EPA Reg. No. 68451-1)

Notification per PR Notice 2007-4

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

Dear Ms. Nesci:

Technology Sciences Group, Inc., on behalf of Intervet Inc., submits the enclosed notification to update the label per PR Notice 2007-4 and to make additional minor text revisions. You will find the following in support of this notification:

- 1) Notification application form,
- 2) One redline version of the revised label, and
- 3) One clean version of the revised label.

Please do not hesitate to contact me with any questions and/or concerns.

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

Sincerely,

Heather R. Bjornson

Regulatory Assistant to Intervet Inc.

Jedna R. Byo-

Direct dial: (202) 828-8945

e-mail: hbjornson@tsgusa.com

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling of the Confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Kills Fleas and Ticks for up to 6 Months LONG LASTING PROTECTION FOR UP TO 6 MONTHS Kills Ticks (including deer ticks which may carry Lyme disease) ALSO KILLS FLEAS

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	<u>96.0%</u>
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT. 0.9 oz

Distributed by: Intervet Inc. 405 State Street Millsboro, DE 19966

Product of France

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

	FIRST AID		
If swallowed	 Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. 		
If on skin or clothing	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice. 		
If in eyes	 Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. 		
Have the produ	For incidents involving HUMANS , call 1-800-680-9206 For incidents involving ANIMALS , call 1-800-548-2423 of container of label with you when calling a poison control center or doctor, or going for treatment.		

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dogs environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacenter variabilis), and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Eymo disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from

the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets. **Pesticide and Container Disposal:** Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx

Universal Product Code Number (Bar Code)

Product if France

NOTIFICATION

JUL 1 7 2009





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

APR 15 2010

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms Patricia A. Sheehy, MS Intervet Inc. 56 Livingston Avenue, R-3-3153G Roseland, New Jersey 07068

Subject: Label Notification(s) for Pesticide Registration Notice 2007-4 and 98-10

Storage & Disposal and other changes

Dear Registrant:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 and 98-10 dated February 23, 2010 for:

EPA Registration 68451-1 Deltamethrin 4% Collar

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and 98-10, and finds that the label change(s) requested falls within the scope of PRN-2007-4 and 98-10. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Banza Diapao of my staff at 703-305-7269.

Sincerely,

Linda Arrington

Notifications & Minor Forwulations Team Leader

a Holloman

Registration Division (7505P) Office of Pesticide Programs

MATERIAL TO BE ADDED TO JACKET

	R	EG#	687	151-1	
Des	cript	tion:	Nothcartion	(for PX)	N 2007-9
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1. Company/Product Number 68451-1 4. Company/Product (Name) Deltamethrin 4% Collar 5. Name and Address of Applicant /Include ZIP Code) Intervet Inc.	ation for Pe	esticide - Sec 2. EPA Product Man Kimberly Nesci PM# PM # 13 3. Expedited Rev	Regist Amen Other tion I	3. Pro	OPP Identifier Number OPP Identifier Number Oposed Classification None Restricted FIFRA Section 3(c)(3) oposition and labeling
56 Livingston Avenue, R-3-3153G Roseland, New Jersey 07068		EPA Reg. No			
✓ Check if this is a new address		Product Name			
	Section	on - II			
Amendment - Explain balow. Resubmission in response to Agency letter dated Notification - Explain balow.		— vflerick lett	Application.	APR 1	
Explanation: Use additional page(s) if necessary. (For sec NOTIFICATION OF DELTAMETHRIN 4% COLLAR PER PR NO changes. This notification is consistent with the guidance in PR 156.144, 156.146, and 156.156. No other changes have been it is a violation of 18 U.S.C. Sec. 10001 to willfully make any fals consistent with the requirements of 40 CFR § 156.10, 156.140, the enforcement action and penalties under sections 12 and 14 or	OTICE 98-10. No Notice 2007-4 ar Notice 2007-4 ar Notice 2007-4 ar Notice 2007-1 Notice 2007-1	offication of label cha did the requirements ing or the Confidentia g statement to EPA. 6, and 156.156, this	of EPA's regulation I Statement of Fo I further understa	ons at 40 CFR to formula for this p and that if the ar	§156.10, 156.140, product, I understand that mended label is not
	Sectio	n - III			
1. Material This Product Will Be Peckaged In: Child-Resistant Packaging Yes No No	Water So		2. Турв	of Container Metal Plastic Glass	
* Certification must be submitted If "Yes" No. per Contains	f "Yes" Peckage v	No. par wgt container		Paper Other (Sp	ecify)
3. Location of Net Contents Information 4. Size(s) Label Conteiner	l Retail Container		5. Location of L	abel Direction	\$
5. Manner in Which Label is Affixed to Product Lith Pap Ste	nogreph per glued inciled	Other .			
	Saction	n - IV			6 6 6 6 4
1. Contact Point	ition of individu	el ta be contected, i	f necessury, to	process this a	oplication.)
Name Patricia A. Sheehy, M.S.	Title Manager, F	Regulatory Affairs		Telephone / - (852) 245-3	Not (Ínclude Ares Code) 3551 - 4
Certifi I certify that the statements I have made on this form a I acknowledge that any knowlingity felse or misleading a both under applicable law.	ind all attachma	nts thereto are true be punishable by fir	, eccurate and c la or imprisonm	onpiate	5. Caté Application Received
2. Signeture		egulatory Affairs			ξ (
4. Typed Name Patricia A. Sheehy, M.S.	5. Date	2-23-2010			

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page: 1 of 4

revision date: 02-23-10

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with 4% Deltamthrin

SCALIBOR® Dog Collar for Flea and Tick Control SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Collar with Deltamethrin

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR ® 6-Month Collar for Dogs SCALIBOR® 6-Month Flea and Tick Collar for Dogs SCALIBOR® 6-Month Flea & Tick Collar for Dogs SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs SCALIBOR® Six Month Flea and Tick Collar for Dogs SCALIBOR® Six Month Flea & Tick Collar for Dogs NOTIFICATION APR 1 5 2010

ACTIVE INGREDIENT: Percentage by Weight Deltamethrin 4.0% INERT INGREDIENTS 96.0% Total 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

ECONOTION OF STREET WITCH

Product of France

Distributed by: Intervet Inc.

67

Roseland, NJ 07068

page: 1 of 4 revision date: 02-23-10

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin SCALIBOR® Collar with 4% Deltamthrin

SCALIBOR® Dog Collar for Flea and Tick Control SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR ® 6-Month Collar for Dogs SCALIBOR® 6-Month Flea and Tick Collar for Dogs SCALIBOR® 6-Month Flea & Tick Collar for Dogs SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs

MOTIFICATION

SCALIBOR® Six Month Flea and Tick Collar for Dogs SCALIBOR® Six Month Flea & Tick Collar for Dogs

APR 15 ZU10

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

Distributed by: Intervet Inc.

Roseland, NJ 07068

Product of France

NET WT. 0.9 oz

page: 2 of 4 revision date: 02-23-10

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

FIRST AID		
If swallowed	 Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. 	
	Do not give anything by mouth to an unconscious person.	
If on skin or	Take off contaminated clothing.	
clothing	 Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice. 	
If in eyes	• Hold eye open and rinse slowly and gently with water for $15-20$,	
	• Remove contact lenses, if present, after the first 5 minutes; then	
	continue rinsing eye.	
	• Call a poison control center or doctor for treatment advice.	
I	for incidents involving HUMANS, call I-800-680-9206	
F	or incidents involving ANIMALS, call 1-800-548-2423	
Have the produ	act container of label with you when calling a poison control center or	
	doctor, or going for treatment.	

page: 3 of 4 revision date: 02-23-10

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis), and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC, warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC, be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx Product if France Universal Product Code Number (Bar Code)

page: 4 of 4 revision date: 02-23-10

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (including deer ticks which may carry Lyme disease)

Kills Ticks (which may carry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name kills fleas and may reduce the incidence of FAD

Kills ticks

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may cause babesiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water

Water resistant





Intervet Schering-Plough Animal Health 556 Morris Avenue, R-3-3151G Summit, NJ 07901-1330 USA T 908-473-3551 F 908-473-3395 www.schering-plough.com

Animal Health

Patricia A. Sheehy Manager, Regulatory Affairs

February 23, 2010

Kimberly Nesci Registration Division (7504P) Office of Pesticide Products US. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

RE:

Deltamethrin 4% Collar (EPA Reg. No. 68451 -I)

Notification per PR Notices 98-10 and 2007-4

Dear Ms. Nesci:

Following my conversation with Melody Banks this morning intervet Inc has removed the statements previously submitted in our December 22, 2009 notification that do not fall within the scope of PR Notice 98-10 and PR Notice 2007-4 related to vector borne diseases. Intervet Inc is providing the enclosed notification to update the label per PR Notices 98-10 and 2007-4.

Notification of Deltamethrin 4% Collar per PR Notice 98-10. "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

Notification of label changed per PR Notice 2007-4 and to make minor text changes. "This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and denay be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

Please find the following documents attached in support of this notification:

- 1) Notification application form,
- 2) One highlighted version of the revised label, and
- 3) One clean version of the revised label.

If you have any questions or comments regarding this submission, please contact me at 862-24543555 for via 6-inail at patricia. sheehy@sp.intervet.com

Sincerely

Patricia. A. Sheeliy, M.S. Manager, Regulatory Affairs

enclosures

Please read instruction	s on reverse before compl	ating form.		Form Appro	ved. DMB No. 20	70-0060	D. Approvel expires 2-28-9		
SEPA	Environmenta	United States al Protection aington, DC 2046	• .		Registrat Amendm Other	on	OPP Identifier Number		
		Application	for Pestici	de - Sectio	n I	<u>,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,</u>	<u> </u>		
1. Compeny/Product No 68451-1	umber			Product Menage rly Nesci) ř	1 7 19	posed Classification		
4. Company/Product (N Deftamethrin 4% Colla	-		PM# PM#	PM# 13					
Intervet Inc. 56 Livingston Ave Roseland, New J	-	oda)	(6)(i), n to: EPA f	ny product is s	imilar or identica	al în cor	FIFRA Section 3(c)(3) appasition and labeling		
			Section -	l					
Amendment - Ex Resubmission in Notification - Ex	response to Agency lette	r deted		Finel printed to Agency letter of "Me Too" App Other - Explain	lication.		TIFICATION PR 1 5 2010		
changes. This notification 156,144, 156,146, and it is a violation of 18 U.S consistent with the requirement.	LTAMETHRIN 4% COLLAR on is consistent with the guid 156.156. No other changes i.C. Sec. 10001 to willfully no irements of 40 CFR § 156.1 and penalties under sections	dance in PR Notice have been made t nake any false and 0, 156.140, 158.1	e 2007-4 and the r o the labeling or th I misleading stater 44, 156,146, and 1	equirements of E re Confidential St ment to EPA. I fur 156.156, this proc	PA's regulations at latement of Formula ther understand that	40 CFR a for this at if the a	§158.10, 156.140, product, Funderstand that mended label is not		
1. Material This Product	t Will Be Packaged In:								
Child-Resistent Peckagin Yes No * Certification mus be submitted	Unit Peckeging Yes No	No. per . container	Water Soluble P Yes No If "Yes" Peckage wgt	No. per container		nteinor Actel Testic Sless aper Other (Sp	oecify)		
3. Location of Net Conte	ents Information	4. Sizo(s) Retail	Conteiner	<u> </u> 5.	Location of Label	Direction	ng		
V Label	Container el is Affixed to Product	Lithograp Peper glu Stencileo	lar net wgt 0.9 o		On carton	uk j	et		
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1. Contact Point /Come	lete items directly below :	for identification	······································		reastury to omen	es this s	vanlication !		
Name Patricia A. Sheehy, M	······································	Т	tio lanager, Regula		Te		No. (Include Area Code)		
	tatements [have made on t zny knowlinglly false or ible law.		ettachments the	_	•		S. Date Application Received (Stamped)		
2. Signature	a Blues	. 1.,	Title anager, Regulator	y Affairs			<i>5</i>		
ed Name		5.1	Date - 2 540 / N:	coulomes	sion of my	nplace	S		

Please read instructions on p	reverse before com <u>inc</u>	g form.		Form Appr	rové	<u> MB No.</u>	<u> 2070-006</u>	O. Approval expires 2-28-9
≎ EPA	Environmental P Washingto	ton, DC 20460			1	Registr Amend Other		OPP Identifier Number
	Aŗ	pplication for	<u>Pestici</u>	ide - Secti	ion I			
1. Company/Product Number 68451-1	r		1	Product Managerly Nesci	ger		3. Pi	roposed Classification
4. Compeny/Product (Neme) Deltamethrin 4% Collar			P M# PM #	13				THOSE THOSE TO SERVICE OF THE SERVIC
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 56 Livingston Avenue, R-3-3153G Roseland, New Jersey 07068 Check if this is a new address			6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No.					
V Chack it this	12 8 UAM BD01932			ict Name				
	**************************************	Sec	ction - i	<u> </u>				· · · · · · · · · · · · · · · · · · ·
Amendment - Explain Resubmission in respo	onse to Agancy letter det	tad	- [] - []	Final printed i Agency letter "Ma Too" Ap Other - Explai	r deted pplicati	d ion.	NOT	THICATION R 1 5 2010
NOTIFICATION OF DELTAM changes. This notification is control of 156.144, 156.146, and 156.15 it is a violation of 18 U.S.C. Se consistent with the requirement to enforcement action and per	consistent with the guidance 56. No other changes have ec. 10001 to willfully make rits of 40 CFR § 156.10, 15	e in PR Notice 2007-4 been made to the lat any fatse and mistea 56.140, 156.144, 156. and 14 of FIFRA	4 and the n beling or th ding stater .146, and 1	requirements of the Confidential (ment to EPA, I f 156,156, this pro	FEPA's Statem further	regulation rent of Fore understand	s at 40 CFF mula for this d that if the	R §156.10, 156.140, s product. I understand that amended label is not
<u> </u>	-	3 80	tion - Il	1]			<u> </u>	
1. Material This Product Will	Be Packaged in:							
Child-Resistant Packaging	Unit Packaging	Water	Solubie P	eckeging	2	2. Type of	Conteiner	
Yes No	Yes No		Yes No				Matal Plastic Glass	
* Certification must be submitted		to per tif "Yes container Packag		No. par containa/		:	Papar Other (5	pecify)
3. Location of Nat Contents in	nformation 4. S	Siza(s) Retail Contai	VOL	5.	Local	tion of Lat	bel Directio	กร
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Name Patricia A. Sheehy, M.S.	and antically paters for the	Title		tory Affairs	7701100		(-4.5.6. 	No (Include Area Code)
I cartify that the statem I acknowledge that eny both under epplicable la	nants I have made on this knowlingity felse or misle	Certification form and all attach eading statement ma	ments the ay be puni	rato are true, dishable by fine	or imp	ite and cor prisonman	cere relicio	6. Date Application Received (Stämped)
2. Signature	Refly.		, Regulator	ry Affairs				61 0 C
Patricia A. Sheehy, M.S.	ne the same of the	5, Date	2-23	3-2010				

page: 1 of 4 revision date: 02-23-10

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin SCALIBOR® Collar with 4% Deltamthrin

SCALIBOR® Dog Collar for Flea and Tick Control SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

;

SCALIBOR & 6-Month Collar for Dogs SCALIBOR® 6-Month Flea and Tick Collar for Dogs SCALIBOR® 6-Month Flea & Tick Collar for Dogs SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs SCALIBOR® Six Month Flea and Tick Collar for Dogs SCALIBOR® Six Month Flea & Tick Collar for Dogs NOTIFICATION

APR 15 2010

ACTIVE INGREDIENT: Percentage by Weight
Deltamethrin 4.0%
INERT INGREDIENTS 96.0%
Total 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET-CONTENTS: 1 Collar

NÈT WT.60.9° oz

Distributed by:

Intervet Inc.

Roseland, NJ 07068

page: 2 of 4 revision date: 02-23-10

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

	FIRST AID					
If swallowed	Call poison control center or doctor immediately for treatment advice.					
	Have person sip a glass of water if able to swallow.					
	• Do not induce vomiting unless told to do so by the poison control center or doctor.					
Do not give anything by mouth to an unconscious person.						
If on skin or	Take off contaminated clothing.					
clothing	• Rinse skin immediately with plenty of water for 15 – 20 minutes.					
	Call a poison control center or doctor for treatment advice.					
If in eyes	 Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. 					
• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.						
	Call a poison control center or doctor for treatment advice.					
F	or incidents involving HUMANS, call 1-800-680-9206					
F	or incidents involving ANIMALS, call 1-800-548-2423					
Have the produ	act container of label with you when calling a poison control center or					
	doctor, or going for treatment.					

page: 3 of 4 revision date: 02-23-10

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis), and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets. **Pesticide and Container Disposal:** Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC, warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx Product if France

page: 4 of 4

revision date: 02-23-10

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (including deer ticks which may carry Lyme disease)

Kills Ticks (which may carry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dematitis (FAD). (Deltamethrin 4% Collar) (alternate brand name kills fleas and may reduce the incidence of FAD

Kills ticks

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may cause babesiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water

page: 1 of 4

revision date: 02-23-10

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin SCALIBOR® Collar with 4% Deltamthrin

SCALIBOR® Dog Collar for Flea and Tick Control SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR ® 6-Month Collar for Dogs SCALIBOR® 6-Month Flea and Tick Collar for Dogs SCALIBOR® 6-Month Flea & Tick Collar for Dogs SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs SCALIBOR® Six Month Flea and Tick Collar for Dogs SCALIBOR® Six Month Flea & Tick Collar for Dogs NOTIFICATION

APR 1 5 2010

ACTIVE INGREDIENT: Percentage by Weight
Deltamethrin 4.0%
INERT INGREDIENTS 96,0%
Total 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements

See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT, 0.9 oz

Distributed by: Intervet Inc.

Roseland, NJ 07068

page: 2 of 4 revision date: 02-23-10

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

	FIRST AID					
If swallowed	 Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. 					
If on skin or clothing • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 – 20 minutes. • Call a poison control center or doctor for treatment advice.						
If in eyes						
Fo	or incidents involving HUMANS, call 1-800-680-9206 or incidents involving ANIMALS, call 1-800-548-2423 or container of label with you when calling a poison control center or doctor, or going for treatment.					

Deltamethrin 4% Collar page: 3 of 4
EPA Reg. No: 68451-1 revision date: 02-23-10

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis), and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC, warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC, MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC, be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx Product if France

page: 4 of 4

revision date: 02-23-10

OPTIONAL/ALTERNATE LABEL TEXT

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Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (including deer ticks which may earry Lyme disease)

Kills Ticks (which may carry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

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Kills ticks

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(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water



Intervet Schering-Plough Animal Health 556 Morris Avenue, R-3-3151G Summit, NJ 07901-1330 USA T 908-473-3551 F 908-473-3395 www.schering-plough.com

m 11 1 01 1

Animal Health

Patricia A. Sheehy Manager, Regulatory Affairs

February 23, 2010

Kimberly Nesci Registration Division (7504P) Office of Pesticide Products US. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

RE: Deltamethrin 4% Collar (EPA Reg. No. 68451 -1)

Notification per PR Notices 98-10 and 2007-4

Dear Ms. Nesci:

Following my conversation with Melody Banks this morning Intervet Inc has removed the statements previously submitted in our December 22, 2009 notification that do not fall within the scope of PR Notice 98-10 and PR Notice 2007-4 related to vector borne diseases. Intervet Inc is providing the enclosed notification to update the label per PR Notices 98-10 and 2007-4.

Notification of Deltamethrin 4% Collar per PR Notice 98-10. "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

Notification of label changed per PR Notice 2007-4 and to make minor text changes. "This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

Please find the following documents attached in support of this notification:

- 1) Notification application form,
- 2) One highlighted version of the revised label, and
- 3) One clean version of the revised label.

If you have any questions or comments regarding this submission, please contact me at 862-245-3551 or via e-mail at patricia.sheehy@sp.intervet.com

Patricia. A. Sheehy, M.S. Manager, Regulatory Affairs

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	Δ	pplication	· · · · · · · · · · · · · · · · · · ·			1	<u> </u>		
1. Company/Froduct Number 68451-1			2. EPA Product Manager Kimberly Nesci			. ہے ا	3. Proposed Classification		
4. Company/Product (Nema) Deitamethrin 4% Collar			PM# PM # 13					Restricted	
5. Name and Address of Applications of Applica		6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name							
Section - II									
Amendment - Explein b		atad		Final printed Agency lette "Me Too" Ag	r date	ed .	to §	VOTIFI	CATION
	Notification - Explain below. APR 1 5 2010						5 2010		
changes. This notification is cor 156.144, 156.146, and 156.156 it is a violation of 18 U.S.C. Sec consistent with the requirement enforcement action and pena	. No other changes hav . 10001 to willfully mak s of 40 CFR § 156.10,	ve been made to to e any false and m 156.140, 156.144, and 14 of F!FRA	he labeling of t risleading state , 155.145, and	he Confidential ment to EPA. I i 156.156, this pr	State furthe	ment of Form or understand	iula for this that if the	s product. I amended !	understand that abel is not
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1. Contact Point (Complete ita	ms directly below for	identification of :	individuel to b	contacted, if	nece	ssary, to pro	cass this	application	r. <i>j</i>
			Title Telephone N Manager, Regulatory Affairs (862) 245-35				ude Area Code)		
f certify that the stateme: I seknowledge that any k both under applicable law	nawlingliy felsa or mi		itacisments the					Receiv	pplication ed amped)
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ped Name Patricia A. Sheehy, M.S.	V O	5. Da	2510 A	couloms	issa is	ion of	eppla	ecités	

Hesse read instructions on reverse peters com	Kath ing form.	leen On	welley Form Approve	2/24/10 . JMB No. 207) 10-0060,	Approvel ex	pires 2-28-5
SEPA Environmenta	United States	on Agency		Registration Amendme Other	on	OPP Identifie	
	Application	on f <mark>or Pestic</mark> í	de - Section	1			
1, Company/Product Number 68451-1			Product Meneger rly Nesci		[nosed Classific	cation Restricted
4. Company/Product (Name) Deltamethrin 4% Collar		PM# PM#	13				nostno (gg
 Name and Address of Applicant Ilnclude ZIP Conference Inc. Livingston Avenue, R-3-3153G Roseland, New Jersey 07068 Chack if this is a new address 	ode)	(b)(i), n to: EPA F	edited Reveiw. ny product is sin leg. No	nilar or identica	J in com	position and	
V JORGEN II IIIS 13 8 1188 8 8 8 118 118 118 118 118 118		Section - I	ct Name				
Amandment - Explain below. Resubmission in response to Agency letter Notification - Explain below. Explanation: Use edditional page(s) if necessar NOTIFICATION OF DELTAMETHRIN 4% COLLAR changes. This notification is consistent with the gestion is a violation of 18 U.S.C. Sec. 10001 to willfully in consistent with the requirements of 40 CFR § 156.1	ry. (For section PER PR NOTI dance in PR Nothave been mad hake any false of 0, 156.140, 156	CE 98-10. Notification tice 2007-4 and the rile to the labeling or the and misleading states 3.144, 156.146, and	equirements of EP/ re Confidential Stat nent to EPA. I furth	etion. efow. per PR Notice 20 Y's regulations at ement of Formula er understand that	APR 07-4 and 40 CFR § 1 for this p	§156.10, 156.1 product. I unde nended label i	r text 40, rstand that s not
no certain action and penalties driver sections	12 8110 14 011	Section - I	l l				
1. Material This Product Will Be Packaged In:							
Child-Resistant Packaging Yes No * Certification must be submitted Unit Packaging (Init Packaging Ves No If "Yes" Unit Packaging wgt	No. per . container	Water Soluble P Yes No If "Yes" Package wgt	No. per container	P	ntainer Metal Yestic Hess Hess Heper Other (Sp	ecify)	
3. Location of Net Contants Information Label Container	4. Size(s) Re	tail Container	5. La	cation of Lebel I	Directions	g	
6. Manner in Which Label is Affixed to Product	Lithog Peper Stenc	graph gluad ifad	Othar			5 6 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6	
		Section - I	/	CKC	τις	<u> </u>	
1. Contect Point (Complete items directly below	for identificatio	on of individual to be	contacted, if nec	essary, to proce	ss this e	op(ii)ation.)	
Name Patricia A. Sheehy, M.S.	<u></u>	Title Manager, Regula	tory Affairs	. (8	£2) 245-3	No. (Include A	(rea Code)
I certify that the statements I have made or I acknowledge that any knowlingily false or both under applicable law.		all attachments the			ata.	J. Data Applic Received	
2. Signature		3. Title Manager, Regulate	ry Affa irs			estr	
4. Typed Name Patricia A. Sheehy, M.S.		5. Date 2-21	3-2010				

page: 1 of 4 revision date: 02-23-10

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin SCALIBOR® Collar with 4% Deltamthrin

SCALIBOR® Dog Collar for Flea and Tick Control SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR ® 6-Month Collar for Dogs SCALIBOR® 6-Month Flea and Tick Collar for Dogs SCALIBOR® 6-Month Flea & Tick Collar for Dogs SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs SCALIBOR® Six Month Flea and Tick Collar for Dogs SCALIBOR® Six Month Flea & Tick Collar for Dogs NOTIFICATION APR 1 5 2010

ACTIVE INGREDIENT: Percentage by Weight
Deltamethrin 4.0%
INERT INGREDIENTS 96.0%
Total 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT. 0.9 oz

Distributed by: Intervet Inc.

Roseland, NJ 07068

page: 2 of 4 revision date: 02-23-10

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

of the property of the propert	FIRST AID				
If swallowed	 Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. 				
If on skin or clothing	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes. Call a poison control center or doctor for treatment & viete. 				
• Hold eye open and rinse slowly and gently with water for 15 - 20 in a minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.					
F	for incidents involving HUMANS, call 1-800-680-9206 or incidents involving ANIMALS, call 1-800-548-2423 act container of label with you when calling a poison control center or doctor, or going for treatment.				

Deltamethrin 4% Collar page: 3 of 4
EPA Reg. No: 68451-1 revision date: 02-23-10

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis), and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx Product if France

page: 4 of 4 revision date: 02-23-10

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (including deer ticks which may carry Lyme disease)

Kills Ticks (which may carry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name kills fleas and may reduce the incidence of FAD

Kills ticks

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may cause babesiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water



page: 1 of 4 revision date: 02-23-10

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Dog Collar for Flea and Tick Control SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR ® 6-Month Collar for Dogs SCALIBOR® 6-Month Flea and Tick Collar for Dogs SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Six Month Collar for Dogs SCALIBOR® Six Month Flea and Tick Collar for Dogs SCALIBOR® Six Month Flea & Tick Collar for Dogs SCALIBOR® Collar with Deltamethrin SCALIBOR® Collar with 4% Deltamthrin

SCALIBOR® Long Lasting Collar for Dogs SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® Protector Band for Dogs

MOTFICATION

APR 15 2000

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg No. 68451-1 EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT. 0.9 oz

Distributed by:

Intervet Inc.

Roseland, NJ 07068

page: 2 of 4 revision date: 02-23-10

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

	FIRST AID					
If swallowed	Call poison control center or doctor immediately for treatme advice.	nŧ				
	Have person sip a glass of water if able to swallow.					
	• Do not induce vomiting unless told to do so by the poison cocenter or doctor.	ontrol				
	Do not give anything by mouth to an unconscious person.	2000				
If on skin or	Take off contaminated clothing.	0000				
clothing	• Rinse skin immediately with plenty of water for 15 – 20 minutés. ***					
_	• Call a poison control center or doctor for treatment advace.					
If in eyes	• Hold eye open and rinse slowly and gently with water for 15	- 20°'·				
-	minutes.					
	• Remove contact lenses, if present, after the first 5 minutes, then					
	continue rinsing eye.	i,				
	Call a poison control center or doctor for treatment advice.	(encic				
F	or incidents involving HUMANS, call 1-800-680-9206	1000 C				
F	or incidents involving ANIMALS, call 1-800-548-2423	* 200				
Have the produ	act container of label with you when calling a poison control cent	ter or				
r	doctor, or going for treatment.					

page: 3 of 4 revision date: 02-23-10

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets. **Pesticide and Container Disposal:** Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC, warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC, be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx Product if France

page: 4 of 4 revision date: 02-23-10

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

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The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dematitis (FAD). (Deltamethrin 4% Collar) (alternate brand name kills fleas and may reduce the incidence of FAD

Kills ticks

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may cause babesiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water



MATERIAL TO BE ADDED TO JACKET

R	EG#	68457-		. 7	
cript	ion:	PRN 2007	7-4 	Reje	ection
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	new st	amped accepte	d lab	el	Send
	new C	i	2		
	notifica	ation			CRC
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	chec	new Cone in the top of the terial in jackets). This material in the e-jacket in hold together with the terial in jacket in Material to be returned.	cription: Check all that apply	check all that apply new stamped accepted label new CSF notification ctions: his sheet to the top of ALL material sent to the file room (botterial in jackets). This sheet will be imaged; a clear descript material in the e-jacket. Remove staples from all material. It is not to be returned to file room should be place in the answer and the state of the	cription: Check all that apply new stamped accepted label new CSF notification Ctions: Inis sheet to the top of ALL material sent to the file room (both loose terial in jackets). This sheet will be imaged; a clear description will a material in the e-jacket. Remove staples from all material. If returning the hold together with a binder or paper clip. CSFs should be placed for (if returning jacket) or covered with a red CBI sheet (if returning Material to be returned to file room should be place in the appropriate the company of the com

Decision Seq. 426587	Action Code: 332,NOTIFICATIO)1t;,30		Decision Status
FFS Start Date	Tentative Ind: No	FFS Original Decision:	<u></u>]	Tracking
Due Date 22-Jan	-2010 75-Day Due Date:	FFS EUP Decision:	<u></u>	Create Resubmission
PP Target Due Dt		FFS Primary Decision.		FFS Letters
legotiated Due Dt.		Start/Stop Clock FQPA Clock:		Welve Documentalio
Registrant sponse Due Date:	<u>liëll</u>	Days Elapsed:		Action Code History
Current Status: PENDIN	3 (21-Jan:2010)			
Decision Comments	Payment	Unmatched Payments	75 Day Lett	ers
Meetings & Milestones	UFFS Information	🧵 FFS Negotiated Due Dates	12 OPP Target	Due Date
Decision Ownership	Receipts	Date Package	∰a Reduced R	isk
Receipts	Staff Member	Reg/DCI Number Submission Di	ie Dt	Response
了S.1865916 Benks N	lelody for	8451-1 22-Jan-201	0 PENDING	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Patricia A. Sheehy Intervet Inc. Corporation 56 Livingston Avenue Roseland, New Jersey 07068

FEB 1 6 2010

Subject: PR Notice 2007-4/Rejection

Deltamethrin 4% Collar EPA Reg. Number: 68451-1 Letter Dated 12/22/09

Dear Ms. Sheehy:

Your original request submitted to the Agency on December 22, 2009, as a Notification, did not clearly fall within the scope of PR Notice 98-10, 2007-4, and has been rejected.

The Optional/Alternate label text on page 4 of 4 requires product performance data to substantiate your propose labeling claims.

You may resubmit your application under an amendment with the appropriate data or data citations to substantiate these claims.

If you have any questions, please contact Melody Banks on 703 305-5413.

\\ ****

Sincerely.

Product Team 10

Insecticide Branch

Registration Division (7505P)

Please Jeso Instructions o	n reverse before com	eting form.	······································	Form Ap	010V6d	OMBN	. 2070-00	60. Approvet expires 2-28-9
\$EPA	SEPA Environmental Protection Weshington, DC 20450				Registra Amanda Other			OPP Identifier Number
		Application	n for Pesti	cide - Sec	tion	l		
1. Company/Product Numb 68451-1	oer		í	A Product Man berly Nesci	eğer			Proposed Classification None Restricted
4. Company/Product (Nam Deltamethrin 4% Collar	#)		PM# PM # 13					
5. Name and Address of A Intervet Inc. Corpora 56 Livingston Avenu Roseland, New Jers	ation Je	ode)	(b)(i) to: EPA	. my product	is sim	ilar or ide	entical in c	th FIFRA Section 3(c)(3) composition and labeling
		·	Section	duct Name			<u></u>	
Amendment - Explain Resubmission in re Notification - Explain	sponse to Agency letter	r dated		Final printe Agency lett "Me Too" Other - Exp	ter dat Applica	ed itios.	NOT	IFICATION B 1 6 2010
it is a violation of 18 U.S.C	AMETHRIN 4% COLLAR s consistent with the guid 1.156. No other changes I . Sec. 10001 to willfully no ments of 40 CFR § 156.1	PER PR NOTICI lance in PR Notice have been made in take any false and 0, 156,140, 156,1	E 98-10. Notifica e 2007-4 and the to the labeling of d misleading sta 144, 156,146, an	tion of label cha e requirements r the Confidentia tement to EPA.	of EPA al State I furthe	's regulation ement of For er understa	ons at 40 Cl ormula for the nd that if th	FR §156,10, 156,140, his product, I understand that
			Section -	111				
1. Material This Product V	/ill Be Peckeyed In:						·····	
Child-Resistent Packeging Yes No	Unit Packaging Yes No		Water Soluble Yes No	Packaging	- · · · · · · · · · · · · · · · · · · ·	2. Type	Metal Plassic Glass	
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per . container	if "Yes" Package wgt	No. per containe	•		Paper Other	(Specify)
3. Location of Nat Content	Container	4. Siza(s) Retai			<u>E</u>	cetion of L	ebel Direct	tions
6. Manner in Which Label	S Affixed to Product	Lithogra Paper gi Stencile	lued d	Othe	r		···	
		· · · · · · · · · · · · · · · · · · ·	Section -		<u> </u>	·····		
1. Contact Point Complet	e items directly below t	for identification	of individual to	be contected.	if nece	ssery, to	process th	is application.)
Name Patricia A. Sheehy, M.S.			Title Manager, Regulatory Affairs			Telepho (862) 24	na No. (Include Area Code) 45-3551	
	isments I have made on my knowlingily false or a law.		il attachments					6. Date Application Received (Stamped)
2. Signettire	1965		. Title Manager, Regut	atory Affairs		, <u></u>		12-23-09
★ Typed Name Patricía A, Sheehy, M.S.		5.	Date 12	2-22-09 (1	بروس	ed t-	8-20to	



Intervet Schering-Plough Animal Health \$56 Morris Avenue, R-3-3151G Summit, NJ 07901-1330 USA T 908-473-3551 F 908-473-3395 www.schering-plough.com

Patricia A. Sheehy Manager, Regulatory Affairs

Animal Health

December 22, 2009 (revised January 5, 2010)

Kimberly Nesci Registration Division (7504P) Office of Pesticide Products US. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

RE: Deltamethrin 4% Collar (EPA Reg. No. 68451 -1) Notification per PR Notices 98-10 and 2007-4

Dear Ms. Nesci:

intervet inc is providing the enclosed notification to update the label per PR Notices 98-10 and 2007-4.

Notification of Deltamethrin 4% Collar per PR Notice 98-10. "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

Notification of label changed per PR Notice 2007-4 and to make minor text changes. "This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

Please find the following documents attached in support of this notification:

- 1) Notification application form,
- 2) One highlighted version of the revised label, and
- 3) One clean version of the revised label.

If you have any questions or comments regarding this submission, please contact me at 862-245-3551 or via e-mail at patricia.sheehy@sp.intervet.com

Sincerely,

Patricia. A. Sheehy, M.S. Manager, Regulatory Affairs

enclosures

page: 1 of 4

revision date: 12-22-09

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

NOTIFICATION

FEB 1 8 2010

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin SCALIBOR® Collar with 4% Deltamthrin

SCALIBOR® Dog Collar for Flea and Tick Control SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR ® 6-Month Collar for Dogs SCALIBOR® 6-Month Flea and Tick Collar for Dogs SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Six Month Collar for Dogs SCALIBOR® Six Month Flea and Tick Collar for Dogs SCALIBOR® Six Month Flea & Tick Collar for Dogs

ACTIVE INGREDIENT: Percentage by Weight Deltamethrin 4.0%INERT INGREDIENTS 96.0%

Total 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements. See Back for additional Precautionary Statements **

Adjustable - One Size Fits All

EPA Est. No. 68451-FRA-1 EPA Reg No. 68451-1

NET CONTENTS: 1 Collar NET WT. 0.9 oz

Distributed by: Intervet Inc. Roseland, NJ 07068

page: 2 of 4 revision date: 12-22-09

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

	FIRST AID
If swallowed	 Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow.
	 Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. Example 1
If on skin or clothing	 Take off contaminated clothing. Rinse skin immediately with plenty of water for \$55-20 minutes. Call a poison control center or doctor for treatment advice.
If in eyes	 Hold eye open and rinse slowly and gently with water for 15 = 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
F	for incidents involving HUMANS, call 1-800-680-9206 or incidents involving ANIMALS, call 1-800-548-2423 act container of label with you when calling a poison control center or doctor, or going for treatment.

page: 3 of 4 revision date: 12-22-09

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis), and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash,

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, returnat once unopened. To the extent consistent with applicable law, INTERVET INC, warrants only that the preduct conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET, INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC, be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx Product if France

page: 4 of 4 revision date: 12-22-09

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (including deer ticks which may carry Lyme disease)

Kills Ticks (which may carry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

Kills ticks

SCALIBOR® protector band the long lasting, easy to use vector borne disease protection for dogs

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water

page: 1 of 4 revision date: 11-20-09

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

NOTIFICATION FEB 1 6 ZUIÜ

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin SCALIBOR® Collar with 4% Deltamthrin

SCALIBOR® Dog Collar for Flea and Tick Control SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR ® 6-Month Collar for Dogs SCALIBOR® 6-Month Flea and Tick Collar for Dogs SCALIBOR® 6-Month Flea & Tick Collar for Dogs SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs SCALIBOR® Six Month Flea and Tick Collar for Dogs SCALIBOR® Six Month Flea & Tick Collar for Dogs

 INERT INGREDIENTS
 96.0%

 Total
 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements.

See Back for additional Precautionary Statements.

Adjustable – One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar NET WT. 0.9 oz

Distributed by: Intervet Inc. Roseland, NJ 07068

page: 2 of 4 revision date: 11-20-09

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

	FIRST AID
If swallowed	 Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control
	 center or doctor. Do not give anything by mouth to an unconscious person;
If on skin or clothing	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 45 = 20 minutes. Call a poison control center or doctor for treatinent advice.
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Ţ.	or incidents involving HUMANS, call 1-800-680-9206
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	doctor, or going for treatment.

page: 3 of 4 revision date: 11-20-09

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis), and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC, warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx Product if France

page: 4 of 4

revision date: 11-20-09

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (including deer ticks which may carry Lyme disease)

Kills Ticks (which may carry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatit (FAD), (Deltamethrin 4% Collar) (alternate brand name kills fleas and may reduce the incidence of FAD

Kills ticks

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may cause babesiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anaplasmosis.

SCALIBOR® Protector Band the long lasting, easy to use vector borne disease protection for dogs

(Deltamethrin 4% Collar) (alternate brand name) the long lasting, easy to use vector borne disesse protection for dogs

(Deltamethrin 4% Collar) (alternate brand name) the long lasting collar easy to use wester borne disease protection for dogs

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water

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Due Date	22-Jan-2010	75-Day Due Date:	FFSE	UP Decision:	•••	Create Resubmission
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Form Approved. OMB No. 2070-0050. Approvel expires 2-28-95

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		Applicatio	n for P	esticio	le - Sect	ion	Ì		
1. Company/Product Number 68451-1	r				roduct Mene ly Nesci	iĝet.			posed Classification None Restricted
4, Compeny/Product (Name) Deltamethrin 4% Collar				PM# 1	3				
5. Name and Address of App Intervet Inc. Corporat 56 Livingston Avenue Roseland, New Jerse V Check if this	ion	de)		(b)(i), m to: EPA R	A blognet is	s simi		in con	FIFRA Section 3(c)(3) apposition and labeling
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Amendment - Explain Resubmission in resp Notification - Explain Explanation: Use eddition NOTIFICATION OF DELTAM	onse to Agency latter below. al paga(s) if nacesser	y. (For section			Agency lette "Me Too" A Other - Expl	tr date pplica sín ba	tion. NO	rific 3 !	ATION 5 2010
changes. This notification is on 156,144, 156,146, and 156,14 it is a violation of 18 U.S.C. Somewhat with the requirement action and performent action ac	consistent with the guide 56. No other changes hec. 10001 to willfully ma ints of 40 CFR § 156.10	ance in PR Notic ave been made ake any false ar 1, 156.140, 156.	ce 2007-4 a to the labe ad misleadi 144, 155.1- RA	and the re aling or the ng statem 46, and 19	quirements o e Confidential ent to EPA. I 56.156, this p	f EPA' State furthe	's regulations at a ment of Formula ir understand tha	i0 CFR for this t if the at	§158.10, 156.148, product, I understand that menided fabel is not
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1. Meterial This Product Will	Se Packaged in:		, <u>.</u>					· · · · · · · · · · · · · · · · · · ·	
Child-Resistant Packaging Yes No * Certification must be submitted	Unit Packaging Yes No No If "Yes" Unit Packaging wgs.	No. par container			No. per container		Pi G Pi	teiner letel lestic less sper ther (Sp	ecify}
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Neme Patricia A. Sheehy, M.S.		1	nde Manager,	Regulat	ory Affairs		1	ephone (2) 245-3	No. (Includa Area Code) 3551
I certify that the states I acknowledge that any both under applicable I	knowlingly false or r		all ettachen					te.	S. Date Application Received (Stamped)
2. Signoture	HS.			rte nager, Regulatory Affairs					19-93-04
Y. Typed Name Patricia A. Sheehy, M.S.			. Date	12-2	2-09 (م	المالية	ed 1-5-2	016)	

EPA Form 8570-1 (Rav. 3-94) Previous editions are obsolete.

White - EPA File Copy (original)

Yellow - Applicant Copy



Intervet Schering-Plough Animal Health 556 Morris Avenuc, R-3-3151G Summit, NJ 07901-1330 USA T 908-473-3551 F 908-473-3595 www.schering-plough.com Animal Health

Patricia A. Sheehy Manager, Regulatory Affairs

December 22, 2009 (revised January 5, 2010)

Kimberly Nesci Registration Division (7504P) Office of Pesticide Products US. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

RE: Deltamethrin 4% Collar (EPA Reg. No. 68451-1)

Notification per PR Notices 98-10 and 2007-4

Dear Ms. Nesci:

Intervet Inc is providing the enclosed notification to update the label per PR Notices 98-10 and 2007-4.

Notification of Deltamethrin 4% Collar per PR Notice 98-10. "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

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Please find the following documents attached in support of this notification:

- 1) Notification application form,
- 2) One highlighted version of the revised label, and
- 3) One clean version of the revised label.

If you have any questions or comments regarding this submission, please contact me at 862-245-3551 or via e-mail at patricia.sheehy@sp.intervet.com

Singerely,

Patricia, A. Sheehy, M.S.

Manager, Regulatory Affairs

enclosures

page: 1 of 4 revision date: 12-22-09

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

NOTIFICATION

Alternate Brand Names:

FEB , is about

SCALIBOR® Flea and Tick Collar for Dogs SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin SCALIBOR® Collar with 4% Deltamthrin

SCALIBOR® Dog Collar for Flea and Tick Control SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR ® 6-Month Collar for Dogs SCALIBOR® 6-Month Flea and Tick Collar for Dogs SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Six Month Collar for Dogs SCALIBOR® Six Month Flea and Tick Collar for Dogs SCALIBOR® Six Month Flea & Tick Collar for Dogs

ACTIVE INGREDIENT: Percentage by Weight Deltamethrin 4.0% INERT INGREDIENTS 96.0% 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

SO 6.6 FW TEKES

Distributed by: Intervet Inc.

Roseland, NJ 07068

page: 2 of 4

revision date: 12-22-09

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

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If on skin or clothing	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes: Call a poison control center or doctor for treatment advice. 		
If in eyes	 Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 trifficutes. then continue rinsing eye. Call a poison control center or doctor for treatment advice. 		
F	or incidents involving HUMANS, call 1-800-680-9206 or incidents involving ANIMALS, call 1-800-548-2423 net container of label with you when calling a poison control center or doctor, or going for treatment.		

page: 3 of 4

revision date: 12-22-09

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

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Part No. xxxxx Product if France

page: 4 of 4 revision date: 12-22-09

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

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Also kills fleas

Kills fleas

Kills ticks

SCALIBOR® protector band the long lasting, easy to use vector borne disease protection for dogs

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water



page: 1 of 4 revision date: 11-20-09

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

NOTIFICATION

FEB 1 6 2010

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Dog Collar for Flea and Tick Control SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR ® 6-Month Collar for Dogs SCALIBOR® 6-Month Flea and Tick Collar for Dogs SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Six Month Collar for Dogs SCALIBOR® Six Month Flea and Tick Collar for Dogs SCALIBOR® Six Month Flea & Tick Collar for Dogs SCALIBOR® Collar with Deltamethrin SCALIBOR® Collar with 4% Deltamthrin

SCALIBOR® Long Lasting Collar for Dogs SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® Protector Band for Dogs

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT. 0.9 oz

Distributed by: Intervet Inc.

Roseland, NJ 07068

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READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID						
If swallowed	Call poison control center or doctor immediately for treatment advice.					
	• Have person sip a glass of water if able to swallow.					
	Do not induce vomiting unless told to do so by the poison control center or doctor.					
	Do not give anything by mouth to an unconscious person.					
If on skin or	Take off contaminated clothing.					
clothing	• Rinse skin immediately with plenty of water for 15 – 20 minutes.					
	• Call a poison control center or doctor for treatment advice.					
If in eyes	• Hold eye open and rinse slowly and gently with water for 15 -20					
·	minutes.					
	• Remove contact lenses, if present, after the first Sminutes, then					
	continue rinsing eye.					
	• Call a poison control center or doctor for treatment advice.					
F	or incidents involving HUMANS, call 1-800-680-9206					
	or incidents involving ANIMALS, call 1-800-548-2423					
	act container of label with you when calling a poison control center or					
	doctor, or going for treatment.					

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DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis), and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC, warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED, WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC, be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duty authorized representative of INTERVET INC.

Part No. xxxxx Product if France

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OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (including deer ticks which may carry Lyme disease)

Kills Ticks (which may earry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatit (FAD). (Deltamethrin 4% Collar) (alternate brand name kills fleas and may reduce the incidence of FAD

Kills ticks

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may cause babesiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anaplasmosis.

SCALIBOR® Protector Band the long lasting, easy to use vector borne disease protection for dogs

(Deltamethrin 4% Collar) (alternate brand name) the long lasting, easy to use vector borne disease protection for dogs

(Deltamethrin 4% Collar) (alternate brand name) the long lasting collar easy to use vector borne disease protection for dogs

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water